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FEDERAL FOOD, DRUG, AND COSMETIC ACT

October 9 (legislative day, October 2), 1990.—Ordered to be printed

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Mr. Kennedy, from the Committee on Labor and Human Resources, submitted the following

REPORT

[To accompany S. 3006]

The Committee on Labor and Human Resources, to which was referred the bill (S. 3006) to amend the Federal Food, Drug, and Cosmetic Act to make improvements in the regulation of medical devices, and for other purposes, having considered the same, reports favorably thereon with an amendment in the nature of a substitute and recommends that the bill as amended do pass.

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The amendment is as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Comprehensive Medical Device Improvement Act of 1990".

SEC. 2. REFERENCES TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.

Except as otherwise specifically provided, whenever in this Act an amendment is expressed in terms of an amendment to a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

S543-31

SEC. 3. REVIEW OF SAFETY AND EFFECTIVENESS INFORMATION.

(a) Review.—Section 510(k) (21 U.S.C. 360(k)) is amended—

(1) by redesignating paragraphs (1) and (2) as subparagraphs (A) and (B), respectively;

(2) by inserting "(1)" after the subsection designation; and

(3) by adding at the end the following new paragraph:

"(2)(A) The requirements of subparagraph (B) shall apply to a person who submits a notification in accordance with paragraph (1) for a device that the person claims is substantially equivalent to a marketed device—

"(i) that was introduced or delivered for introduction into interstate commerce for commercial distribution before the date of enactment of this paragraph;

"(ii) that is classified as a class III device in accordance with subsections (b) through (d) of section 513; and

"(iii) for which no final regulation requiring premarket approval has been promulgated in accordance with section 515(b).

"(B) A person described in subparagraph (A) shall—

"(i) prior to the submission of a notification in accordance with paragraph (1), conduct a reasonable search for, and review of, published and unpublished data available to the person concerning the safety and effectiveness of the marketed device and the device for which the notification is submitted, including all adverse safety and effectiveness data concerning the devices, except for data that has been submitted to the Secretary in accordance with section 519 of this Act and section 803 of title 21, Code of Federal Regulations; and

"(ii) include in the notification a certification that the search and review was conducted and a citation to and summary of the data resulting from the search.

"(C) The Secretary may require the submission of any data described in the summary required by paragraph (B)(ii).".

SEC. 4. CLASSIFICATION OF DEVICES.

(a) Classification.—Section 513 (21 U.S.C. 360c) is amended—

(1) in subsection (a)(1)—

(A) in subparagraph (A)(ii), by striking "or to establish a performance standard" and inserting "or to establish an additional control or controls, as described in subparagraph (B)(ii),";

(B) by amending subparagraph (B) to read as follows:

"(B) Class II, additional controls.—A device—

"(i) that cannot be classified as a class I device because general controls are insufficient to provide reasonable assurance of the safety and effectiveness of the device;

"(ii) for which there is sufficient information to establish an additional control or controls to provide the assurance, including—

"(I) promulgating a performance standard;

"(II) developing and disseminating a guideline, including a guideline for the submission of clinical data in a premarket notification submission in accordance with section 510(k);

"(III) requiring the use of postmarket surveillance as appropriate in accordance with section 522; and

"(IV) making a recommendation or taking other appropriate action considered necessary by the Secretary to provide reasonable assurance of the safety and effectiveness of the device; and

"(iii) for which it is necessary to establish an additional control or controls to provide reasonable assurance of the safety and effectiveness of the device;

except that for a device that is purported or representated to be for a use in supporting or sustaining human life, sufficient information must exist for the Secretary to identify and describe the provision of a performance standard to provide such assurance."; and

(C) in subparagraph (C)(i)(II), by striking "establishment of a performance standard" and inserting "establishment of an additional control, as described in subparagraph (B)(ii),"; and

(2) in subsection (f)—

(A) in paragraph (1), by inserting "the Secretary by order determines that" after "unless"; and

(B) in paragraph (2), by striking "The" and inserting "The Secretary may initiate the reclassification of a device classified in class III under paragraph (1), or a".

(b) Conforming Amendment.—Section 513(h)(1) is amended by inserting after "510" the following: "(except for a guideline for the submission of clinical data in a premarket notification submission in accordance with section 510(k))".

SEC. 5. REVISION OF CLASSIFICATION FOR CERTAIN CLASS III DEVICES.

(a) Revision of Classification.—Section 513 (21 U.S.C. 360c) (as amended by section 4(b) of this Act) is further amended—

(1) by redesignating subsection (h) as subsection (i); and

(2) by inserting after subsection (g) the following new subsection:

"Revision of Classification

"(h)(1) The requirements established by order in accordance with paragraph (2) shall apply with respect to a device—

"(A) that was introduced or delivered for introduction into interstate commerce for commercial distribution before the date of enactment of this subsection;

"(B) that is classified as a class III device; and

"(C) for which no final regulation requiring premarket approval has been promulgated in accordance with section 515(b).

"(2) Not later than 36 months after the date of enactment of this subsection, the Secretary—

"(A) shall by order require manufacturers of devices described in paragraph (1) to submit to the Secretary a citation to and summary of all published and unpublished data reasonably available to the manufacturer concerning the safety and effectiveness of the device, including any adverse safety and effectiveness data, except for information that has been submitted to the Secretary under section 519 of this Act and section 803 of title 21, Code of Federal Regulations; and

"(B) may require a manufacturer to submit any data described in the summary.

"(3) After the issuance of an order in accordance with paragraph (2)(A), but not later than 24 months after the issuance of the order, the Secretary shall publish in the Federal Register for each device covered by the order a notice of proposed rulemaking proposing to change the classification of the device to class II or to class I or to continue the classification of the device in class III.

"(4) In determining whether to revise the classification of a device or to continue the classification of the device in class III, the Secretary shall apply the criteria in section 513(a) to the information available when the device was initially classified and any new information made available since initial classification.

"(5) After considering any comments submitted in response to the notice of proposed rulemaking, the Secretary shall issue a final regulation changing the classification of the device or continuing the classification in class III. The Secretary shall publish in the Federal Register findings on the matters referred to in paragraph (4), a discussion of the comments received in response to the notice of the proposed rulemaking, and the response of the Secretary to the comments. The Secretary shall publish the final regulation not earlier than 90 days, and not later than 12 months, after the date of publication of the notice of proposed rulemaking relating to the regulation.

"(6) A regulation issued in accordance with paragraph (5) is subject to judicial review in accordance with section 517.

"(7) Not later than 12 months after the effective date of any regulation issued in accordance with paragraph (5), the Secretary shall establish a schedule for the issuance of a regulation in accordance with section 515(b) requiring submission of a premarket approval application for each device that has been continued in class III.".

SEC. 6. ESTABLISHMENT OF PERFORMANCE STANDARDS.

(a) Procedure.—Section 514 (21 U.S.C. 360d) is amended—

(1) in subsection (a), by striking "The Secretary may" and inserting "If the Secretary determines that a performance standard is necessary to provide reasonable assurance of the safety and effectiveness of a class II device, the Secretary shall";

(2) by striking subsections (b) through (f);

(3) by redesignating subsection (g) as subsection (b);

(4) in subsection (b) (as redesignated), by striking paragraphs (1) and (2) and inserting the following new paragraphs:

"(1)(A) The Secretary shall publish in the Federal Register a notice of proposed rulemaking for the establishment, amendment, or revocation of any performance standard for a device.

"(B) A notice of proposed rulemaking for the establishment or amendment of a performance standard for a device shall—

"(i) set forth a finding with supporting justification that the performance standard is appropriate and necessary to provide reasonable assurance of the safety and effectiveness of the device;

"(ii) set forth proposed findings with respect to the risk of illness or injury that the performance standard is intended to reduce or eliminate;

"(iii) invite interested persons to submit to the Secretary within 30 days of the publication of the notice, requests for changes in the classification of the device based on new information relevant to the classification; and

"(iv) invite interested persons to submit an existing performance standard for the device, including a draft or proposed performance standard, for consideration by the Secretary.

"(C) A notice of proposed rulemaking for the revocation of a performance standard shall set forth a finding with supporting justification that the performance standard is no longer necessary to provide reasonable assurance of the safety and effectiveness of a device.

"(D) The Secretary shall provide for a comment period of no fewer than 60 days.

"(2) If, after publication of a notice in accordance with paragraph (1), the Secretary receives a request for a change in the classification of the device, the Secretary shall, within 60 days of the publication of the notice, consult with a classification panel described in the second sentence of section 513(e).".

(b) Conforming Amendments.—

(1) Section 514(b) (as redesignated by subsection (a)(3)) is amended—

(A) in paragraph (3)(A), by striking "paragraph (2)" and inserting "paragraph (1)"; and

(B) in paragraph (4)(A), by striking "paragraphs (2) and (3)(B)" and inserting "paragraphs (1), (2), and (3)(B)".

(2) Section 517(a)(3) (21 U.S.C. 360g(a)(3)) is amended by striking "514(b)(2) or".

(3) Section 520(i) (21 U.S.C. 360j(i)) is amended by striking "514(g)(5)(B)" and inserting "514(b)(5)(B)".

SEC. 7. SUSPENSION OF APPROVAL OF APPLICATION.

Section 515(e) (21 U.S.C. 360e(e)) is amended by adding at the end the following new paragraph:

"(3)(A) The Secretary may by order suspend the approval of an application approved under this section if the Secretary determines that there is a reasonable probability that the continued distribution of a device under the application would cause serious, adverse health consequences or death.

"(B) Not less than 10 days prior to the issuance of a suspension order under subparagraph (A), the Secretary shall issue a notice that the Secretary shall provide the holder of the application for the device with an opportunity for an informal hearing to determine whether to issue the order.

"(C) Not more than 10 days after the hearing described in subparagraph (B), the Secretary shall issue a suspension order or determine that the order should not be issued.

"(D) Not more than 20 days after the issuance of the suspension order, the Secretary shall issue a notice initiating the process of withdrawal of approval of the application, as described in paragraphs (1) and (2). If the Secretary does not issue the notice within the specified time frame, the suspension order shall be deemed to be vacated.".

SEC. 8. JUDICIAL REVIEW.

Section 517(a) (21 U.S.C. 360g(a)) is amended—

(1) by striking "or" at the end of paragraph (6); and

(2) by inserting after paragraph (7) the following new paragraphs:

"(8) the issuance of a regulation under section 513(h), or

"(9) the issuance of an order under section 513(f)(1) or an order effectuating the classification required under 520(l)(1)(D).".

SEC. 9. EMERGENCY RECALL AUTHORITY.

Section 518 (21 U.S.C. 360h) is amended by adding at the end the following new subsection:

"Emergency Recall Authority

"(e)(1) If the Secretary finds that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death, the Secretary shall issue a recall order. The order shall require the appropriate party or parties (including the manufacturers, importers, distributors, or retailers of the device) to immediately cease any distribution of the device and, thereafter, recall the device from commercial distribution.

"(2)(A) The order issued under paragraph (1) shall include recall of devices from hospitals and other health care institutions, unless the Secretary determines that the risk of recalling the device from the facilities presents a greater health risk than not recalling the device from use.

"(B) For devices subject to an order issued under paragraph (1), and in lieu of including individuals within the recall order, the Secretary shall order a notification under subsection (a) regarding the risks associated with the continued use of the device to individuals or, when appropriate, the health professionals who prescribed the device for the use of the individuals.

"(3) Not later than 10 days after the issuance of a recall order, the Secretary shall provide the party or parties to whom the order is directed with the opportunity for an informal hearing to determine whether the order shall be affirmed or vacated.

"(4) If, after providing an opportunity for an informal hearing, the Secretary determines that the recall order was properly issued, the order shall remain in effect. The order shall specify a timetable in which the device recall will occur, and shall require periodic reports to the Secretary describing the progress of the recall effort.

"(5) If, after providing an opportunity for an informal hearing, the Secretary determines that inadequate grounds exist to support the order issued under paragraph (1), the Secretary shall vacate the order.

"(6) A party to whom the recall order is issued shall—

"(i) remedy the causes that resulted in the issuance of the order;

"(ii) complete the recall in accordance with the order; and

"(iii) submit a report to the Secretary demonstrating compliance with the order.

"(7) After fulfilling the requirements of paragraph (6), a party to whom the recall order is issued may petition the Secretary to vacate the order. The petition shall state the basis for vacating the order.

"(8) The Secretary shall respond to the petition described in paragraph (7) not later than 30 days after the receipt of the petition. If the Secretary finds that the party to whom the recall order was issued has fulfilled the requirements of paragraph (6) and that the device may be distributed in interstate commerce, the Secretary shall vacate the order.

"(9) The remedy provided by this subsection shall be in addition to those provided by subsections (a), (b), and (c).".

SEC. 10. USER REPORTS.

(a) **Requirement**.—Section 519 (21 U.S.C. 360i) is amended—

(1) in subsection (a)(3), by inserting before the semicolon the following: "and shall require distributors who submit the reports to submit copies of the reports to the manufacturer of the device for which the report was made";

(2) by adding at the end the following new subsections:

"Inclusion of Distributors

"(c) Not later than 1 year after the date of the enactment of this subsection, the Secretary shall amend the regulations promulgated under this section to require distributors of medical devices to establish and maintain records and make reports under this section. In amending the regulations, the Secretary may exempt classes of distributors from whom reports are not necessary for the protection of the public health.

"Certification

"(d) Each manufacturer, importer, and distributor required to make reports under subsection (a) shall submit to the Secretary annually a statement certifying that the manufacturer, importer, or distributor—

"(1) did not file any report; or

"(2) did file a certain number of the reports.

"User Reports

"(e)(1) As used in this subsection:

"(A) The terms 'facility' and 'medical device user facility' mean a hospital, nursing home, or ambulatory surgical facility.

"(B) The terms 'serious illness' and 'serious injury' mean illness or injury, respectively, that is unanticipated and—

"(i) is life threatening;

"(ii) results in permanent impairment of a body function or permanent damage to a body structure; or

"(iii) necessitates immediate medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

"(2) If a medical device user facility becomes aware of information that reasonably suggests that a medical device has caused or contributed to the death of a patient of the facility, the facility shall, as soon as practicable but not later than 15 working days after becoming aware of the information, report the information to the Secretary and, if the identity of the manufacturer is known, to the manufacturer of the device.

"(3) If a medical device user facility becomes aware of information that reasonably suggests that a medical device has caused or contributed to a serious illness or serious injury to a patient of the facility, the facility shall, as soon as practicable, but not later than 15 working days after becoming aware of the information, report the information to the manufacturer of the device. If the facility is unable to determine the identity of the manufacturer of the device, the facility shall send a report of the information to the Secretary.

"(4) For purposes of paragraphs (2) and (3), a medical device user facility shall be treated as having received or otherwise become aware of information with respect to a medical device of the facility when appropriate medical personnel employed by or otherwise affiliated with the facility receive or otherwise become aware of information with respect to the device in the course of the duties of the individual.

"(5)(A) Except as provided in subparagraph (B), the Secretary may not disclose the identity of a facility that makes a report in accordance with paragraph (2) or (3)—

"(i) except in connection with an action brought to enforce section 301(q);

"(ii) except in connection with a communication to a manufacturer of a device that is the subject of a report in accordance with paragraph (2) or (3); or

"(iii) unless required to be disclosed in accordance with subsection (a).

"(B) This paragraph shall not authorize the Secretary to withhold the identity of a facility making a report in accordance with paragraph (2), or any information in the report, from duly authorized committees and subcommittees of Congress.

"(6)(A) No report made in accordance with paragraph (2) or (3) by a person described in subparagraph (B) shall be admitted into evidence in any civil action involving private parties unless the person had knowledge of the falsity of the information contained in the report.

"(B) As used in subparagraph (A), the term 'person' means—

"(i) a medical device user facility;

"(ii) one of the appropriate medical personnel employed by or otherwise affiliated with the facility; or

"(iii) a physician who is not required to make a report in accordance with paragraph (2) or (3).

"(7) The obligation of a medical device user facility to make a report in accordance with paragraph (2) or (3) shall not affect the obligation of the manufacturer of the device who receives the information to file a report concerning the device as required under subsection (a).

"User Education

"(f)(1) During the 1-year period beginning on the date of enactment of this subsection, the Secretary may award grants to eligible entities to establish public education programs for hospitals, ambulatory surgical facilities, and nursing homes concerning the user reporting requirements set forth in subsection (e).

"(2) In awarding grants in accordance with paragraph (1), the Secretary shall give priority to entities to submit proposals that demonstrate—

"(A) a need for user education among hospitals, ambulatory surgical facilities, and nursing homes regarding a generic category of medical device; and

"(B) the ability to adequately perform the proposed educational program.

"(3) In order to receive a grant in accordance with paragraph (1), an entity shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may by regulation require. At a minimum, the application shall contain—

"(A) a description of the proposed public education program;

"(B) the qualifications and experience of the entity to carry out the program; and

"(C) the need for user education among persons to be served by the entity regarding a generic category of medical device.

"(4) The Secretary shall by regulation specify the qualifications for an entity to receive a grant in accordance with paragraph (1).

"(5) There are authorized to be appropriated to carry out this subsection such sums as may be necessary for each of fiscal years 1991 through 1993.".

(b) REGULATIONS.—The Secretary of Health and Human Services shall promulgate regulations to implement section 519(e) of the Federal Food, Drug, and Cosmetic Act, as added by the amendment made by subsection (a), not later than 12 months after the date of enactment of this Act. In promulgating the regulations, the Secretary shall minimize the administrative burdens on medical device user facilities consistent with the need to assure adequate information.

(c) REPORT TO CONGRESS.—Not later than 36 months after the date of enactment of this Act, the Secretary of Health and Human Services shall prepare and submit to the appropriate committees of Congress a report that contains an evaluation of the requirements of section 519(e) of the Federal Food, Drug, and Cosmetic Act. In preparing the report, the Secretary shall consult with individuals and organizations with an interest in health care and consumer issues. At a minimum, the report shall contain—

(1) an evaluation of the safety benefits of the requirements;

(2) an evaluation of the burdens placed on the Food and Drug Administration and on medical device user facilities by the requirements;

(3) an evaluation of the cost-effectiveness of the requirements; and

(4) recommendations for legislative reform.

(d) EFFECTIVE DATE.—Section 519(e) of the Federal Food, Drug, and Cosmetic Act shall become effective on the earlier of—

(1) the effective date of regulations promulgated in accordance with subsection (b); or

(2) the date that is 12 months after the date of enactment of this Act.

SEC. 11. REPORTS OF REMOVALS AND CORRECTIVE ACTIONS.

Section 519 (21 U.S.C. 360i) (as amended by section 10 of this Act) is further amended by adding at the end the following new subsection:

"Reports of Removals and Corrective Actions

"(g)(1)(A) Except as provided in paragraph (2), the Secretary shall by regulation require a manufacturer, importer, or distributor of a device to report promptly to the Secretary any removal or corrective action of a device undertaken by the manufacturer, importer, or distributor of a device if the removal or corrective action was undertaken to—

"(i) eliminate a significant risk to health caused by the device; or

"(ii) remedy a violation of this Act caused by the device which may present a risk to health.

"(B) A manufacturer, importer, or distributor of a device who undertakes a corrective action or removal of a device that is not required to be reported under subparagraph (A) shall keep a record of the corrective action or removal.

"(2) No report of the corrective action or removal of a device may be required under paragraph (1) if a report of the corrective action or removal is otherwise required under this Act, or the corrective action or removal was initiated at the request of the Secretary, and a report has been submitted to the agency.

"(3) For purposes of paragraphs (1) and (2), the terms 'corrective action' and 'removal' do not include routine servicing.".

SEC. 12. USE OF PREMARKET APPROVAL DATA.

Section 520 (21 U.S.C. 360j) is amended—

(1) in subsection (c)—

(A) by striking "under section 513 from class III to class II" and inserting "from class III to class II or class I"; and

(B) by inserting "in accordance with subsection (h) and" after "reclassified from class III to class II, except"; and

(2) in subsection (h)—

(A) in paragraph (3), by striking "Any" and inserting "Except as provided in paragraph (4), any"; and

(B) by adding at the end the following new paragraph:

"(4)(A) Any information contained in an application for premarket approval filed with the Secretary pursuant to section 515(c), including clinical and preclinical tests or studies, but excluding descriptions of methods of manufacture and product composition, that demonstrates the safety and effectiveness of a device shall be available 1 year after the original application for the fourth device of a kind has been approved by the Secretary, for use by the Secretary in approving devices, or determining whether a product development protocol has been completed, under section 515, establishing a performance standard under section 514, and reclassifying devices under subsections (e) and (f) of section 513, and subsection (l)(2). The Secretary shall deem devices that incorporate the same technologies, have the same principles of operation, and are intended for the same use or uses to be within a kind of device.

"(B) The Secretary, contemporaneously with the approval of the fourth device of a kind, shall publish a notice in the Federal Register identifying the four devices of a kind that have been approved under section 515 and the date on which the data contained in premarket approval applications for the devices will be available to the Secretary for use, as described in subparagraph (A). For each device described in subparagraph (D)(i)(I), the Secretary shall publish a notice in the Federal Register setting forth the date, which shall be not earlier than 1 year after the date of notice, that data identified in subparagraph (A) shall be available for the use of the Secretary.

"(C) The publicly available detailed summaries of information respecting the safety and effectiveness of devices required by paragraph (1)(A) shall be available for use by the Secretary as the evidentiary basis for—

(i) approving devices, or determining whether a product development protocol has been completed, under section 515;

(ii) establishing a performance standard under section 514; and

(ii) reclassifying devices under subsections (e) and (f) of section 513, and subsection (l)(2).

"(D)(i) This paragraph shall become effective—

"(I) upon the date of the enactment of the paragraph, for devices approved under section 515, where four devices of a kind were approved on or before December 31, 1987; and

"(II) 24 months after the date of the enactment of the paragraph, for devices not included within the scope of subclause (I) that are subject to a premarket approval requirement under section 515.

"(ii) For each device described in subparagraph (D)(i)(II) for which the original application for a fourth device of a kind is approved by the Secretary before the 24-month delayed effective date described in subparagraph (D)(i)(II), the 24-month delayed effective date shall be deemed to be the approval date for the fourth device of a kind.

"(E) The approval date of a device, for purposes of this paragraph, shall be the date of the letter of the Secretary to the applicant approving a device under section 515, and permitting the applicant to commercially distribute the device.".

SEC. 13. TRACEABILITY.

Section 520(j) (21 U.S.C. 360j(j)) is amended to read as follows:

"Traceability Requirements

"(j)(1) The Secretary shall, not later than 1 year after the date of enactment of this subsection, determine which devices should be subject to a requirement of labeling, or coding, or identification by any other means, that is necessary to ensure that the device may be traced from the place of manufacture of the device or initial distribution to the ultimate user of the device, from among devices that—

"(A) are permanent implants;

"(B) are purported or represented to be for use in supporting or sustaining human life; or

"(C) present a potential unreasonable risk of illness or injury.

"(2) Not later than 2 years after the date of enactment of this subsection, the Secretary shall by regulation require the manufacturers, importers, and distributors of the devices that are described in paragraph (1) to establish the means by which the devices will be traced to the ultimate user.".

SEC. 14. REVISION OF CLASSIFICATION FOR DEVICES REGULATED AS NEW DRUGS OR ANTIBIOTIC DRUGS.

(a) IN GENERAL.—Section 520(l)(2) (21 U.S.C. 360j(l)(2)) is amended—

(1) by inserting "(A)" after the paragraph designation; and

(2) in subparagraph (A) (as designated by paragraph (1), by striking "The" and inserting "The Secretary may initiate the reclassification of a device classified in class III under paragraph (1), or a"; and

(3) by adding at the end the following new subparagraph:

"(B)(i) Not later than 90 days after the date of enactment of this subparagraph, the Secretary shall publish a notice in the Federal Register with respect to devices that are subject to regulation pursuant to this subsection. The notice shall state whether each device shall remain in class III or be reviewed for classification into class I or II. The notice shall also require the manufacturer of a device that the Secretary intends to classify into class I or II to submit to the Secretary a description of and citation to any adverse safety and effectiveness information not submitted under section 519(a) of this Act and section 803 of title 21, Code of Federal Regulations. The Secretary may require a manufacturer to submit the adverse safety and effectiveness information for which a description and citation were submitted to the Secretary.

"(ii) After the issuance of the notice under clause (i), and following consultation with appropriate advisory panels in accordance with subsections (b) through (d) of section 513, but before the expiration of the 1-year period beginning on the date of enactment of this subparagraph, the Secretary shall publish a proposed regulation in the Federal Register classifying each device into class I or II, or providing that each device shall remain in class III. The data furnished by manufacturers in accordance with clause (i), in combination with the advice and recommendation of appropriate advisory panels shall, for purposes of this Act, serve as a basis for satisfying the criteria set forth in subclause (I) or (II) of section 513(a)(1)(C)(ii), and shall serve as a basis for the proposed regulation required under this subparagraph.

"(iii) Following a review of comments received on the proposed regulation issued in accordance with clause (ii), and before the expiration of the 1-year period referred to in clause (ii), the Secretary shall promulgate a final regulation prescribing the classification of all devices regulated under this subsection on the date of enactment of this subparagraph. No regulation issued under this subparagraph requiring a device to remain in class III or classifying the device as class I or II may take effect before the expiration of 90 days from the date of the publication of the regulation in the Federal Register.

"(iv) The Secretary may by notice in the Federal Register extend the 1-year period prescribed by clauses (ii) and (iii) for a device for an additional period not to exceed 1 year.

"(v) Notwithstanding any other provision of this subsection, the Secretary shall not retain any daily wear nonhydrophilic plastic contact lens in class III unless the Secretary finds that it meets the criteria set forth in subclause (I) or (II) of section 513(a)(1)(C)(ii). The finding, and the grounds for the finding, shall be published in the Federal Register. If during the 1-year period beginning on the date of enactment of this subparagraph, the Secretary has not made the finding and issued the notice required by this clause, the Secretary shall issue an order placing the lens in class II.

"(vi) Actions taken under this subparagraph shall not interfere with any pending reclassification action. Any device for which a reclassification petition was pending on January 1, 1989, shall not be included in the list published under clause (i).".

(b) CONFORMING AMENDMENT.—Section 520(l)(1) is amended—

(1) by inserting "on the initiative of the Secretary or" after "Secretary"; and

(2) by striking "paragraph (2)" and inserting "paragraph (2)(A)".

SEC. 15. SUBSTANTIAL EQUIVALENCE.

Section 520 (21 U.S.C. 360j) is amended by adding at the end the following new subsection:

"Substantial Equivalence

"(m)(1) For purposes of determinations of substantial equivalence under this subchapter—

"(A) The term 'different technological characteristics' means, with respect to a device being compared to a predicate device, that there is a significant change in the materials, design, energy source, or other features of the device from those of the predicate device.

"(B) The term 'substantially equivalent' or 'substantial equivalence' means, with respect to a device being compared to a predicate device, that the device has the same intended use as the predicate device and—

"(i) has the same technological features as the predicate device; or

"(ii) has different technological features and the evidence submitted that the device is substantially equivalent to the predicate device contains information, including clinical data, if required, that demonstrates that the device is as safe and effective as a marketed device.

"(2) A device may not be found to be substantially equivalent to a predicate device that has been removed from the market at the initiative of the Secretary or that has been determined to be misbranded or adulterated by a judicial order.

"(3) The Secretary shall promulgate regulations under which a manufacturer seeking a determination of substantial equivalence may be required to prepare a summary of any clinical data required (including information respecting any adverse effects of the device on health) if the Secretary determines that clinical data must be submitted in accordance with paragraph (1)(B)(ii), and establishing a standard format for the summary. The Secretary shall make the summary available to the public within 30 days of the issuance of a determination of substantial equivalence.".

SEC. 16. HUMANITARIAN DEVICE EXEMPTION.

Section 520 (21 U.S.C. 360j) (as amended by section 15 of this Act) is further amended by adding at the end the following new subsection:

"Humanitarian Devices

"(n)(1) It is the purpose of this subsection to encourage the discovery of devices intended to benefit patients in the treatment or diagnosis of rare diseases or conditions, to the extent consistent with the protection of the public health and safety and with ethical standards.

"(2) As used in this subsection, the term 'rare disease or condition' means any disease or condition that affects fewer than 8,000 persons in the United States. Determinations under the previous sentence with respect to any device shall be made on the basis of the facts and circumstances as of the date of submission of an application under paragraph (3).

"(3) Not later than 8 months after the date of enactment of this subsection, the Secretary shall promulgate regulations prescribing procedures and conditions under which persons may on application be granted an exemption for devices from the effectiveness requirements of section 502, 514, 515, 516, 519, or 706, or subsection (e) or (f) of this section, to permit the use of the devices by physicians in the treatment of patients afflicted by a rare disease or condition.

"(4) In promulgating regulations under paragraph (3), the Secretary may prescribe procedures and conditions under which an exemption may be granted for a device if—

"(A) the device is likely to provide a significant benefit to a patient in the treatment or diagnosis of a disease or condition, or a significant benefit to the patient in quality of life;

"(B) the device is used—

"(i) in the treatment or diagnosis of a rare disease or condition and cannot reasonably be expected to be available absent the exemption; or

"(ii) the patient population affected by the disease or condition is not sufficient to conduct clinical trials of the effectiveness of the device; and

"(C) the Secretary determines that the probable benefit to health from the use of the device outweighs the risk of injury or illness from the use and the probable risks and benefits of currently available devices or alternative forms of treatment.

"(5) Devices granted an exemption under this subsection shall only be used—

"(A) in facilities that have established, in accordance with regulations of the Secretary, a local institutional review committee to supervise clinical testing of devices in the facilities; and

"(B) if, prior to the use of a device, an institutional review committee approves the use in the treatment or diagnosis of a specific rare disease or condition.".

SEC. 17. POSTMARKET SURVEILLANCE.

The Act is amended by inserting after section 521 (21 U.S.C. 360k) the following new section:

"SEC. 522. POSTMARKET SURVEILLANCE.

"(a) IN GENERAL.—

"(1) REQUIRED SURVEILLANCE.—The Secretary shall require a manufacturer to conduct postmarket surveillance for any device that—

"(A) is a permanent implant the failure of which may cause serious, adverse health consequences or death:

"(B) is intended for a use in supporting or sustaining human life; or

"(C) presents potential for serious risk to human health.

"(2) DISCRETIONARY SURVEILLANCE.—The Secretary may require a manufacturer to conduct postmarket surveillance for a device if the Secretary determines that postmarket surveillance of the device is necessary to protect the public health or to evaluate the safety or effectiveness of the device.

"(b) REGULATIONS.—The Secretary shall issue regulations implementing the requirements of this section not later than 1 year after the date of enactment of this section.

"(c) SURVEILLANCE PERIOD.—The Secretary may determine the period of surveillance required in order to complete the collection of useful data or other information necessary to protect the public health or to evaluate the safety or effectiveness of the device. In no event may a surveillance period be imposed in accordance with this section without a termination date.

"(d) CONTRACTS.—

"(1) IN GENERAL.—The manufacturer of a device for which postmarket surveillance is required in accordance with subsection (a) shall contract with a qualified academic medical center, or a representative number of qualified academic medical centers in representative locations, to provide for any monitoring of clinical experience that may be required in accordance with this section.

"(2) LACK OF QUALIFIED ACADEMIC MEDICAL CENTER.—If no academic medical center has the qualifications and experience to conduct adequate monitoring of clinical experience in accordance with this section, a manufacturer shall contract with a qualified medical center or with a representative number of qualified medical centers in representative locations to provide the monitoring.

"(3) NUMBER AND IDENTITY.—The manufacturer shall determine, and obtain the approval of the Secretary regarding, the number and identity of the center or centers that will perform surveillance in accordance with this section and the manner of surveillance.

"(e) APPLICATION.—This section shall apply only to devices that are first distributed in interstate commerce after the date of enactment of this section.".

SEC. 18. ESTABLISHMENT OF THE OFFICE OF INTERNATIONAL RELATIONS.

Section 801 (21 U.S.C. 381) is amended by adding at the end the following new subsection:

"(f)(1) The Secretary may enter into agreements with foreign governments, which agreements specify that devices of either country that are manufactured in accordance with rules and regulations for device manufacture under this Act are suitable for commercial distribution.

"(2) In entering into the agreements described in paragraph (1), the Secretary shall encourage the mutual recognition of—

"(A) good manufacturing practice regulations promulgated under section 520(f)(1)(A); and

"(B) other rules, regulations, and testing protocols as the Secretary determines to be appropriate.

"(3) The Secretary shall establish an Office of International Relations that shall plan and initiate programs for the recognition of devices in accordance with paragraph (1).

"(4) The Secretary may issue regulations to carry out this subsection.

"(5) Not later than 2 years after the date of enactment of this subsection, the Secretary shall prepare and submit to the appropriate committees of Congress a report on the activities of the Office of International Relations.".

SEC. 19. DEFINITIONS.

Section 201 (21 U.S.C. 321) is amended—

(1) in subsection (g)(1), by striking "; but does not include devices or their components, parts, or accessories"; and

(2) in the language following paragraph (3) of subsection (h), by striking "any of its principal" and inserting "its primary".

SEC. 20. REVIEW OF MARKET APPLICATIONS FOR ARTICLES COMPRISING COMBINATIONS OF DRUGS, DEVICES, AND BIOLOGICS.

Section 503 (21 U.S.C. 353) is amended—

(1) by striking the section heading and inserting the following:

"EXEMPTIONS AND CONSIDERATION FOR CERTAIN DRUGS, DEVICES, AND BIOLOGICAL PRODUCTS";

and

(2) by adding at the end the following new subsection:

"(f)(1) The Secretary shall designate a component of the Food and Drug Administration to regulate products that constitute a combination of a drug, device, or biological product. The Secretary shall determine the primary mode of action of the combination product. If the Secretary determines that the primary mode of action is that of—

"(A) a drug (other than a biological product), the persons charged with premarket review of drugs shall have primary jurisdiction;

"(B) a device, the persons charged with premarket review of devices shall have primary jurisdiction; or

"(C) a biological product, the persons charged with premarket review of biological products shall have primary jurisdiction.

"(2) Nothing in this subsection shall prevent the Secretary from using any agency resources of the Food and Drug Administration necessary to ensure adequate review of the safety, effectiveness, or substantial equivalence of an article.

"(3) The Secretary shall promulgate regulations to implement market approval procedures in accordance with paragraphs (1) and (2) not later than 1 year after the date of enactment of this subsection.

"(4) As used in this subsection:

"(A) The term 'biological product' has the meaning given the term in section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)).

"(B) The term 'market clearance' includes—

"(i) approval of an application under section 505, 507, 515, or 520(g);

"(ii) a finding of substantial equivalence under this subchapter; and

"(iii) approval of a product or establishment license under subsection (a) or (d) of section 351 of the Public Health Service Act (42 U.S.C. 262).".

SEC. 21. NEW DRUG APPROVAL.

Section 505(j) (21 U.S.C. 355) is amended by adding after paragraph (7) the following new paragraph:

"(8) The Secretary may not approve an abbreviated application for new drug approval under this subsection for a period of 10 years from the date of the approval of the listed drug, if the listed drug—

"(A) is an anti-inflammatory, non-steroidal drug; and

"(B) is a drug for which an application under subsection (b) was submitted on or before March 29, 1982, and approved on or after October 31, 1988.".

SEC. 22. PATENTS.

Section 156 of title 35, United States Code, is amended—

(1) in subsection (a)—

(A) in paragraph (2), by inserting ", except as otherwise provided in subsection (i)" after "extended"; and

(B) in the second sentence, by inserting ", and in subsection (i)", after "and (5)"; and

(2) by adding at the end the following new subsection:

"(i)(1) Notwithstanding the provisions of subsection (a)(2), if a claim or claims of any patent on an invention that was conceived or reduced to practice substantially in the performance of work at a nonprofit organization cover more than one product, or a method of using or manufacturing more than one product, that is subject to a regulatory review period before the commercial marketing or use of the product, the claim or claims may be separately extended as to each of the products in accordance with this section.

"(2) In no event may any extensions granted under this subsection extend the term of a patent claim in respect of a product other than a product for which extension is sought.

"(3) As used in this subsection, the term 'nonprofit organization' has the meaning given the term in section 201(i).".

I. PURPOSE AND SUMMARY OF BILL

The purpose of this bill (S. 3006) is to improve the Medical Device Amendments of 1976 (Amendments), the first legislation to put in place a comprehensive framework to regulate medical devices and to ensure their safety and effectiveness. Through a unique classification system, the Amendments divided devices into three classes so that the most appropriate level of regulatory oversight would control the entry of devices into commerce, while still assuring the American people safe and effective products. Simply put, the law sought to avoid overregulation, thus eliminating unnecessary resource costs to industry and the government, foster incentives to encourage innovation in a relatively youthful industry and, most importantly, provide the public reasonable assurance of safe and effective devices.

While implementation of the Amendments by the Food and Drug Administration (FDA) has led to a substantial improvement in the safety and effectiveness of devices, refinement of the law is necessary to achieve the original purposes of the Amendments. For example, experience has shown that FDA has not had the ability to provide the degree of consumer protection necessary to avoid situations where potentially life-threatening devices remain on the market. This situation has occurred either because the FDA is not made aware of a device's risk in a timely fashion or the agency has knowledge of a defective device but is unable to respond quickly.

On the premarket side of device regulation, S. 3006 responds to the current weaknesses of the law. Numerous provisions in the bill are intended to enhance device safety and effectiveness. The premarket review process will be made more effective by clarifying the appropriate classification of devices, thus avoiding over-regulation and the needless expenditure of FDA resources. The premarket review process will also be strengthened by codifying FDA's interpretation of the premarket notification process, and by assuring adequate documentation for Class III pre-Amendments predicate devices which are not yet subject to regulations requiring a premarket approval application (PMA). Additionally, the bill permits the agency, on a one time basis, to reconsider the classification of all pre-Amendments and transitional Class III devices to determine whether judgments made fourteen years ago are appropriate. Moreover, S. 3006 will require the agency to set a firm schedule for promulgating regulations that call for PMAs for pre-Amendments devices, thus closing the loophole now present in the statute.

Other improvements in premarket regulation relate to streamlining the law and making regulation more efficient. The bill streamlines the process of promulgating performance standards and, more specifically, defines those devices to which performance standards apply. Class II is redefined so that the Secretary will be better able to reclassify devices out of Class III, while assuring safety and effectiveness with means other than performance standards, including, additional controls such as guidelines or postmarket surveillance.

The bill also permits the Secretary access to previously unavailable safety and effectiveness data for use in approving and reclassifying devices, and for establishing performance standards. S. 3006, therefore, enables the Secretary to avoid meaningless duplication in the premarket review process, and, likewise, provides the Secretary with the means of moving classes of devices out of the resource intensive premarket review arena.

On the postmarket side of the safety and effectiveness equation, S. 3006 provides additional means to protect the public health. The bill provides mechanisms that will greatly expand FDA's device experience information base. Reporting requirements of device-related serious injuries and deaths from hospitals, nursing homes, or ambulatory surgical facilities, and reports of device removals and corrections, will provide the Secretary with access to valuable information not previously available. S. 3006 gives the Secretary discretion to require postmarket surveillance studies for certain devices, and mandates that such studies be done for the devices posing the most significant risks.

S. 3006 enhances postmarket protections through a device tracing provision which empowers the Secretary to promulgate regulations to trace devices from their origin to the ultimate user. Coupled with the ability to trace a device to its ultimate user, the bill provides the Secretary authority to recall devices that may cause serious adverse health consequences or death and also to halt their distribution. The bill further empowers the Secretary to suspend, after an informal hearing, FDA approvals of certain Class III devices which may cause serious, adverse health consequences or death.

S. 3006 responds directly to the lessons learned from implementing and enforcing the Amendments. Three themes dominate S. 3006: (1) enhancing the safety and effectiveness of devices by defining and better streamlining the premarket review mechanisms, and by creating a web of postmarket controls that alert the FDA to device problems and provide the means for responding quickly and effectively to situations that may present serious, adverse health consequences; (2) preserving and focusing FDA resources on the most important public health issues associated with medical device regulation; and (3) avoiding over-regulation, thus maintaining a highly competitive, innovative industry.

II. Background and Need for Legislation

A. WEAKNESSES IN THE PREMARKET REVIEW PROCESS

Despite the large challenge to the FDA of implementing and enforcing the Amendments, the agency has done a commendable job of assuring the American public that worthwhile devices are available, notwithstanding significant resource constraints relative to the task at hand. The FDA faced an enormous task in essentially starting from scratch in regulating devices, nonetheless, there is significant concern that Congress' original intent of eventually subjecting all Class III and Class II devices to premarket controls has not been fulfilled.

FDA's interpretation of the Amendments, and its exercise of discretion in initiating rulemakings to require PMAs for pre-Amendments Class III devices and the establishment of performance standards for Class II devices, has created an unintended "grandfather" provision. Specifically, the section 510(k) premarket notification requirement, which requires a person who must register to notify the FDA at least 90 days before marketing a device, functions to classify post-Amendments devices. Classification for these devices is achieved by determining whether a device is "substantially equivalent" to a pre-Amendments device. If the newer device is "substantially equivalent" to a predicated device, then the newer device will be classified and regulated in the same manner as the predicate. If, however, the newer device is not "substantially equivalent" to the predicate device, then the newer device will automatically be placed into Class III by operation of law.

Over 95% of the devices marketed since the passage of the Amendments have been found "substantially equivalent" to a predicate device. Since the FDA has required relatively few PMAs for pre-Amendments Class III devices, and since the agency has not to date promulgated a performance standard under the Act (FDA has promulgated performance standards that apply to radiation emitting devices under the Radiation Control for Health and Safety Act of 1968), newer devices that are "substantially equivalent" to pre-Amendments Class III or Class II devices are effectively grandfathered from the regulation appropriate to their classification.

Importantly, the Committee's concern with FDA's interpretation and implementation of the Amendments relates more to a difference in degree than kind. Although the 510(k) premarket notification requirement is far more important than the Committee had expected it to be, we will not second guess FDA's interpretation of the Act in light of the difficult resource situation the agency faces, and the fact that the premarket notification program has proved to be a reasonable screen for identifying unsafe or ineffective devices. However, to the extent section 510(k), or any other section, has perpetuated a loophole in the statute that interferes with the appropriate regulation of important devices, there is a need to expeditiously close the loophole and assure that all devices are regulated consistent with the expectations of Congress.

B. WEAKNESSES IN POSTMARKET SURVEILLANCE MECHANISMS

Over the past several years reports from the General Accounting Office (GAO) and Office of Technology Assessment, as well as Congressional hearings, have shown that reporting to the FDA of potentially serious device hazards has been incomplete. (GAO/PEMD-87-1: "Medical Devices—Early Warning of Problems Is Hampered by Severe Under-reporting). Extensive information from legislative hearings and elsewhere regarding the Bjork-Shiley 60 degree Convexo-Concave heart valve show that, despite the manufacturer's knowledge of of unexpected device failures and deficiencies in its manufacturing process, the FDA did not timely receive the information necessary to promptly initiate regulatory actions to protect the public or to inform those persons implanted with the value what measures should be taken to minimize their risk.

GAO has documented a significant weakness in FDA's information gathering ability and its follow-up mechanisms, once information is in hand. For example, although the FDA has received more than a seven-fold increase in reports associated with device-related problems since the promulgation of the Medical Device Reporting

Regulation (MDR), it appears there is under-reporting of device-related reportable events and that many firms subject to the regulation are unaware of their obligation to report device-related deaths, serious injuries, and malfunctions to the FDA. (GAO/PREMD-89-10: "Medical Device—FDA's Implementation of the Medical Device Reporting Regulation"). Additionally, GAO has further documented that device reporting has been weak even for the most significant events, those related to a risk of serious injury or death. GAO found that only 50% of Class I recalls, the recall classification associated with device-related serious adverse health consequences or death, were documented by medical device reports. (GAOP/PEMD-89-15BR: "Medical Device Recalls—An Overview and Analysis 1983-88").

The Committee has concern that although the FDA has mandatory notification and recall authority under section 518 of the Act, the agency has neither ordered a notification to persons subject to a risk nor a recall, including repair or replacement of, or reimbursement for devices. The Committee acknowledges that the FDA has a reasonable record in encouraging voluntary recalls; however, the agency's failure ever to use its authority under section 518 is symptomatic of a weak information base to support aggressive regulatory action and a hesitance to use authority that is inadequately streamlined to permit quick and efficient regulatory responses.

III. History of Legislation

S. 3006 was introduced by Senator Kennedy for himself and Senators Hatch, Dodd, Coats and Durenberger on August 4, 1990, and referred to the Labor and Human Resources Committee.

Prior to introduction, the Committee had held a hearing on July 25, 1990 concerning ways to improve the regulation of medical devices. The following individuals presented testimony:

James S. Benson, Acting Commissioner, Food and Drug Administration, Rockville, Maryland;

Sidney M. Wolfe, M.D., Director, Public Citizen Health Research Group, Washington, D.C.;

Alan Magazine, President, Health Industry Manufacturers Association, Washington, D.C., accompanied by Edwin H. Allen, Vice-President and General Counsel;

Kevin V. Ryan, Chairman, Contact Lens Institute, Sunnyvale, California;

Earl Saltzgiver, President, Foremost Contact Lens Service Inc., Salt Lake City, Utah.

The witnesses offered comments on draft legislation that the Committee was considering. Many of these comments were incorporated in the bill as introduced. Most sections of the draft legislation have been retained in the bill, some with substantial alterations. The section of the introduced bill dealing with "remanufactured" devices, however, has been deleted because the FDA already has authority in this area; where the agency exercises this authority, the Committee expects FDA to recognize that there are many different types of activities in the used medical device marketplace and that regulatory requirements may differ for each.

IV. COMMITTEE VIEWS

SECTION 3. REVIEW OF SAFETY AND EFFECTIVENESS DATA

The Committee believes that this provision, calling for data summaries on pre-Amendments Class III devices, and their substantially equivalent post-Amendments devices, represents an appropriate response to the dilemma created by FDA's failure to call for full reviews of safety and effectiveness data on the vast majority of pre-Amendments Class III devices. The Committee views the requirement of conducting a reasonable search and review of safety and effectiveness data for these devices as an interim measure until the FDA completes its classification of all pre-Amendments Class III devices, and issues regulations requiring PMAs under Section 515(b).

In requiring summaries of safety and effectiveness data, the Committee does not in any manner intend to create the impression that such summaries will serve as substitutes for PMAs and full safety and effectiveness reviews. The Secretary is also authorized to require the submission of clinical and non-clinical data cited in the summary and the Committee expects the Secretary to do so if questions exist concerning the comparable safety and effectiveness of newer and marketed devices.

SECTION 4. CLASSIFICATION OF DEVICES

The inability of the Secretary to issue a single performance standard in the 14 years since the Amendments, demonstrates the need to create a more flexible regulatory framework for Class II devices. The Committee's decision to broaden the definition of Class II devices reflects a recognition, based on experience, that mandatory performance standards are not necessary for the regulatory of all devices for which Class I controls are insufficient.

However, the Class II definition for life sustaining and life supporting devices will continue to reference a performance standard, plus general controls, as the means of reasonably assuring safety and effectiveness. Consistent with existing law, it is not the intention of the Committee to require that a performance standard must exist before such devices are placed in Class II, but the Committee does believe that there must be sufficient information available to allow the Secretary to identify and describe a performance standard.

Nonetheless, the Committee expects that performance standards will be established where appropriate. The ability of FDA to establish such standards should be significantly enhanced in light of the simplified requirements for establishing performance standards contained elsewhere in this legislation.

The Committee feels that it is important to clarify that the Secretary has the authority to initiate a reclassification of "new" devices automatically placed into Class III by operation of law under section 513(f)(1) of the Act, when it is in the interest of the public health. The legislation, therefore, expressly states the Secretary's standing to initiate a reclassification under 513(f)(2).

SECTION 5. REVISION OF CLASSIFICATION FOR CERTAIN CLASS III DEVICES

Although the Secretary has up to six years to revise classifications and issue a schedule for promulgating regulations requiring PMAs for Class III pre-Amendments devices, it is of profound importance to the Committee that the revision of classifications and the regulations requiring PMAs be completed as quickly as possible. The time-frames in this section have been formulated with due regard for the resource demands on FDA; however, the agency should make every effort to complete the process for pre-Amendments Class III devices before the expiration of the six year period. Further, the Committee anticipates that once the FDA established PMA regulation schedules, the process will be executed in a timely manner. The Committee notes that the issuance of 515(b) regulations for pre-Amendments Class III devices includes the requirement that all devises that are substantially equivalent to them must submit PMAs to FDA, and receive approvals or be removed from commercial distribution.

The Committee believes it is appropriate to provide FDA with the opportunity to reevaluate its earlier classifications of pre-Amendments devices in the light of its regulatory experience, and with the benefit of current data. However, FDA's failure to aggressively regulate pre-Amendments Class III devices has been unacceptable, and the agency must require PMAs for those devices which will remain in Class III.

SECTION 6. ESTABLISHMENT OF PERFORMANCE STANDARDS

The Committee believes that by simplifying the process for establishing performance standards, and by allowing the Secretary discretion to employ such standards as one of a variety of "additional controls" to assure the safety and effectiveness of Class II devices, performance standards will become valuable tools to regulate those devices for which they are most needed. The Committee anticipates that streamlining the standards-setting process will permit FDA to use performance standards as the effective regulatory control that Congress envisioned for them in the Amendments.

In his testimony before the Committee on July 25, 1990, acting FDA Commissioner James Benson stated the agency's support for a law that would permit the agency, given its resource limitations, to promulgate a performance standard regulation. Now the FDA has such a law.

SECTION 7. SUSPENSION OF APPROVAL OF APPLICATION

The Committee believes that providing the Secretary with authority to act quickly to revoke a PMA in emergency situations is an important improvement to the Act. Experience shows that proceedings to withdraw drug approvals (there have been no fully contested withdrawals of device premarket approval applications) are extremely time consuming, and the product at issue has remained on the market during the pendency of the withdrawal proceeding. The Act and regulations governing the withdrawal of approval of device applications do not suggest that the process will be any more expeditious than a drug application withdrawal and, short of pursuing a parallel proceeding in district court, no expeditious means now exist to remove dangerous devices from the market.

The standard for the issuance of a suspension order is "a reasonable probability that the continued distribution of a device under the application would cause serious, adverse health consequences or death." The Committee believes that a "reasonable probability" of the occurrence of an event is one where it is more likely than not that the event will occur. The Secretary will have considerable discretion in determining whether it is more likely than not that the continued distribution of a device would cause serious, adverse health consequences or death.

What constitutes "serious, adverse health consequences" is a crucial concept not only for this section but sections 9 and 17. The Committee believes that this term should mean any significant adverse experience attributable to a device, including those which may be either life threatening, or involve permanent or long-term injuries, but excluding those non-life-threatening injuries which are temporary and reasonably reversible. In other words, injuries attributable to a device that are not significant in nature and are treatable and reversible by standard medical techniques, proximate in time to the injury, are not included within the term's definition.

SECTION 8. JUDICIAL REVIEW

The Committee is aware that under the Administrative Procedure Act the Secretary's determinations of the classification of "new" or transitional devices constitute orders subject to judicial review. Section 4 of the bill amends section 513(f)(1) to eliminate any questions that a device is automatically in Class III, requiring a PMA, unless the Secretary finds that it is substantially equivalent to a device which is not subject to a premarket approval requirement. These views conform with district court decisions, see *United States* v. *Clark Research and Development Inc.*, Civil Action No. 89-3201 (ED La. 1989); *United States* v. *An Article of Device * * * Stryker Shoulder 130-10 Dacron Ligament Prostheses,* 607 F. Supp. 990 (WD Mich. 1985), and the text of the current status.

By explicitly stating that the Secretary's action is an order, the Committee hopes to reinforce the Secretary's correct interpretation of the Act that the 90-day notification period, specified in section 510(k), is a limitation imposed on marketers of devices and not the Secretary. The Committee does not expect that inserting the words "The Secretary by order determines that" in section 513(f)(1) of the Act should have any effect on how the agency conducts its business in classifying devices intended for commercial distribution.

SECTION 9. EMERGENCY RECALL AUTHORITY

There was Committee consensus that it was necessary to provide the Secretary with explicit authority to institute emergency recalls of devices which posed unacceptable risks. In the 14 years since the Amendments, the "repair, replacement, or refund" provisions of section 518(b) of the Act have never been used. Section 518(b)'s intricate findings and procedures have served as an inappropriate deterrent to its use. In response to questioning from Committee members at the July 25, 1990 hearing, Acting FDA Commissioner

Benson acknowledged that the agency would be more likely to use a simplified and strengthened recall authority to protect the public, if such authority was made available to the agency. The Committee believes that section 9 provides the agency a highly useful tool.

The Committee worked closely with the regulated industry to craft statutory language which allows for prompt action to protect the public health, while assuring the rights of the person subject to the recall order. The standard for the recall—reasonable probability that a device would cause serious, adverse health consequences or death—was the result of considerable negotiations, and is discussed in the Committee's views of section 7.

Additionally, the Secretary is required to provide parties to whom the order is directed with the opportunity for a hearing no later than 10 days after the issuance of the recall order. The bill does not have specific timetables under which recalls must occur, although earlier drafts of the legislation did provide such timetables; the Committee believes that it is more appropriate to allow the Secretary, dependent on the circumstances of each case, to establish the time-frames for completion of the recall.

The Committee notes that the purpose for this section is to provide the means for a rapid response to an emergency situation. Once the Secretary has made the requisite findings, it is essential that the recall be initiated and completed as quickly as possible. The Committee expects that the requirement that parties subject to the recall order must make periodic reports to the Secretary on the progress of the recall effort will ensure that the Secretary can identify, and immediately remedy, any unnecessary delays in compliance.

The emergency recall authority is in addition to other remedies in section 518 of the Act, including patient notification under subsection 518(a). Direct patient notification under subsection 518(a) will be used in conjunction with an emergency recall order, and the bill restates that subsection's strong presumption in favor of such direct notification. It is recognized that in those cases where direct patient notification is not appropriate, notification through a health professional may be necessary.

SECTION 10. USER REPORTS

The medical device user facility reporting provisions of S. 3006 are central to meaningful reform of medical device law. Although the MDR regulations have substantially increased information about adverse experiences with devices, the GAO has documented that device problems in hospitals are rarely reported. Perhaps the most startling evidence came in a 1986 GAO report which showed that less than 1% of device problems occurring in hospitals were reported to FDA. (GAO/PEMD-87-1). Of even greater concern was GAO's finding in the same study that the more serious the problem with the device, the less likely hospitals were to report the incident. A GAO follow-up study in 1989 concluded that despite full-scale implementation of the MDR regulations, serious shortcomings in reporting persist. (GAO/PEMD-89-10).

The Committee believes that it is not sensible to exclude medical facilities, such as hospitals, from reporting requirements for serious device problems when significant numbers of devices are routinely used in such facilities. Moreover, many new, and potentially risky, devices are first used in hospitals and similar facilities.

A comprehensive system that captures the vital device information that such facilities can provide is a prerequisite to improving the regulation of medical devices. Sensitive to the concerns of medical device user facilities, FDA, and device manufacturers about the additional burdens created by this section, the Committee has tried to narrow the reporting requirements to those incidents of greatest importance. By restricting the scope of reporting to only those circumstances where there is a reasonable suggestion that a device has caused or contributed to a serious illness or injury, or a death, the Committee also intends to eliminate any requirements that facilities must speculate about risks that have not yet occurred.

Section 10 requires that when a medical device user facility becomes aware of information, which reasonably suggests that a medical device has caused or contributed to the death of a patient, or has caused or contributed to a serious illness or injury to a patient, the facility will report this information as soon as practicable, but not later than 15 working days after becoming aware of the information.

The bill directs the Secretary to promulgate regulations within one year of enactment implementing the new user reporting requirements, and the Secretary is instructed to do so in a manner that minimizes the administrative burdens on medical device user facilities. The Secretary is directed to assure, to the extent practicable, that the new user reporting requirements do not unduly increase this burden.

It is the Committee's belief that the time-frame required for user reporting will provide a sufficient period to allow user's to prepare accurate, concise, and useful reports. In the event of a death or a serious illness/injury, the Committee realizes that the tendency of a facility facing too tight a deadline might be to attribute any adverse effect to the device. However, 15 working days will provide more than adequate time to avoid such over-reporting.

The Committee does not expect that user reports would be filed on the mere belief that a reportable event has occurred. It is not the intention of the Committee that user facilities be held responsible for reporting information that does not reasonably suggest that a device has caused or contributed to a serious illness, injury, or death.

A facility's obligation to report will begin at the time it "becomes aware" of a medical device's role in the death, injury, or illness of the patient. The Committee believes that a facility "becomes aware" of a reportable event at the time that appropriate medical personnel at the facility receive the requisite information to make a report.

In response to the concerns of FDA that resource constraints would make it very difficult for the agency to process reports made in accordance with this section, the Committee has required direct reports to FDA only in the case of device-related deaths. Serious illnesses or injuries that may be associated with devices are to be reported to FDA, only if the manufacturer cannot be identified. This bill, of course makes no changes in the requirements of section 519(a) of the Act nor in the MDR regulation. Manufacturers who receive reports from medical device user facilities are responsible for reviewing the reports and, where appropriate, filing MDR reports with FDA.

The Committee has provided protections to persons and entities making reports under this section in order to encourage complete reporting. For example, the identity of facilities making the reports is disclosable by the Secretary only with respect to certain enforcement actions under the Act, communications with device manufacturers, or responses to Congressional inquiries. This section also specifies that there is no prohibition against disclosure when the reported event is also required to be disclosed under section 519(a) of the Act. The Committee intends this provision to clarify that this bill will not affect public access to information in MDR reports. To the extent that a single event engenders an initial report by a medical device user facility, in accordance with this section, and a subsequent MDR report by a manufacturer, the information contained within the report of the facility would be protected, while the information contained within the MDR would be available to the public as under current law.

The bill provides that reports made by facilities in accordance with this section are not admissible into any civil action involving private parties. The only exception is for reports submitted by persons with knowledge of a report's falsity. The bill does not, of course, prohibit civil actions based upon the underlying events that are the subject of a report.

The bill extends the protection against civil actions to physicians who are not otherwise required to make reports under the provisions of the legislation. It is the intent of the Committee to encourage physicians to make reports about problems with devices, even if they re not affiliated with a facility subject to reporting requirements.

The bill requires that within one year of its enactment, the Secretary will include distributors of medical devices within the scope of the mandatory device reporting regulation. The bill also provides the Secretary with discretion to exempt classes of distributors from reporting, when it is unnecessary to protect the public health. The Committee recognizes that there are certain classes of distributors that would not receive information related to safety or health problems because of the nature of their products or their markets. The Committee expects that the Secretary will focus the reporting requirement on those distributors that are in a position to receive information about problems with medical devices or whose products are likely to raise public health concerns.

The bill provides authority to the Secretary to establish grants to educate facilities about the new reporting requirements. The Committee believes that it is important that the Secretary initiate such education efforts as quickly as possible after the bill's enactment in order to prevent a reoccurrence of the types of difficulties encountered after promulgation of the MDR regulation, where several years after the regulations took effect, over one-third of covered persons were reportedly unaware of the existence of the MDR regulation. (GAO/PEMD 89-10)

Importantly, the Committee included a requirement that device manufacturers, importers, and distributors must submit annual certifications on the numbers of MDR reports submitted to FDA, or the fact that no reports were submitted. The Committee notes that this regulation is directly in response to a GAO finding that certification would increase the efficiency of the NDR system.

The bill requires the Secretary, in consultation with appropriate health care and consumer organizations, to submit a report to the appropriate committees of Congress outlining the safety benefits of the new reporting requirements, and evaluating the administrative burdens attributable to the bill placed on medical device user facilities and the FDA. The Committee believes that such a report, which the Secretary must submit within three years of enactment, will provide practical information about how best to minimize unnecessary administrative requirements while assuring the availability of vital information about device-related health problems.

SECTION 11. REPORTS OF REMOVALS AND CORRECTIVE ACTIONS

The Committee included this section in the bill to assure that the Secretary has current and complete information regarding those actions taken to eliminate risk to health caused by devices. The Committee is aware that the FDA has never required a recall activity under section 518(b) of the Act, and has relied exclusively on voluntary recalls.

Notwithstanding the general acceptance by the agency and industry of a voluntary approach, the FDA and others have expressed concern that manufacturer initiated device removals and corrections are made without timely notification, or no notification, to the agency. A failure promptly to include the FDA in these significant postmarket activities denies the agency the opportunity to fulfill its its public health responsibilities by evaluating device-related problems and the adequacy of corrective actions.

In order to assure the agency complete and timely information regarding device removal or corrective actions, without creating over-reporting, the bill requires reports to the Secretary of the more imporant postmarket actions, excluding those events already reported to the Secretary. For removals or corrective actions not required to be reported to the Secretary, records must be maintained and, therefore, will be available to the Secretary at a later time.

The definitions of the terms "significant risk to health" and "risk to health," and the word "promptly" are important to the operation of this section. The Committee intends, for purposes of this section, that a "significant risk to health" means that the risk of harm to the persons to whom the device is intended is likely and not remote, and that the harm being avoided is neither insubstantial nor trivial. A "risk to health" that may result from a violation of the Act means that the risk of harm to a person for whom the device is intended exists, and the harm is not trivial. The Committee intends that the word "promptly" means that a report required under this shall be filed not later than 10 days after the initiation of a removal or a corrective action.

Although the Committee has not required the Secretary to promulgate a regulation by a time certain, it is our expectation that the Secretary will propose a regulation implementing this section no later than one year after the enactment date of this legislation. The Committee notes that the FDA has extensive experience with device removals and corrections and, given the guidance provided in this report, believes that a one year time-frame for a proposed regulation is reasonable.

SECTION 12. USE OF PREMARKET APPROVAL DATA

The Committee believes this section will be highly important to the agency's overall success in implementing the many new obligations placed on it by this legislation. To be as efficient as possible, the agency must have the ability to reclassify devices and avoid the significant cost of premarket application reviews, assessed at approximately 1200 hours per application on the average, unless an assurance of device safety and effectiveness requires such a review. Numerous products, including, for example, non-hydrophilic contact lenses, remain in Class III because under current law only publicly available information may be used to reclassify a device. Now, the Secretary can avoid unnecessary, resource intensive PMA reviews, and over-regulation, by using previously protected data to determine the appropriate classification of devices.

Additionally, permitting the Secretary access to PMA data avoids the needless expense to the FDA of repeatedly reviewing information in subsequent PMAs that becomes unnecessary to assure device safety and effectiveness. Of course, to the extent the Secretary can, based on available PMA data, rely on past approvals to eliminate requirements in subsequent PMAs, savings will accrue to applicants. Also, PMA data, once available for the Secretary's use, may be helpful in minimizing costs to the FDA in other proceedings specified in section 12, such as the establishment of a performance standard.

The Committee believes that this change in the law is justified apart from the obvious resource savings to FDA that will result. Nowhere else in the Act are safety and effectiveness data protected in the manner prescribed by the Amendments. The original purpose behind the Amendments' absolute prohibition on the use of PMA data was to support a relatively youthful industry and create incentives to foster innovation. This need was particularly important since the Amendments require the disclosure of detailed summaries of safety and effectiveness data and, without protection, the summaries could be used by competitors to minimize the innovator's return on investment in product research and development. Fourteen years later, the Committee believes that the Amendments' absolute protection of safety and effectiveness data is no longer justified since the device industry is now mature and strong. Moreover, it is neither in the industry's nor consumer's interest to unnecessarily require either PMAs for Class III devices that should be reclassified or repetitive submissions of PMA data that are no longer significant to demonstrating device safety and effectiveness. Continuation of either situation will in the long-term injure industry and the public health by delaying approval decisions on the newest and likely most important products.

The Committee believes that section 12 represents a beneficial compromise between device firms' interest in maintaining protection of their PMA data, thus maintaining a competitive advantage, and the FDA's interest in having access to PMA data to determine whether the reclassification of the device is feasible.

It is the Committee's view that section 12 will provide a degree of protection to device firms roughly proportionate to the size of a firm's investment. Specifically, since the disclosure of data is dependent upon the approval of a fourth device of a kind, the time it will take to achieve four approvals will largely relate to the novelty and complexity of a device. Newer and more complex technologies will likely involve greater commitments of time and money and, therefore, the Committee believes that substantially longer periods of data protection will result for the early developers of complex technologies, which should encourage innovation. Where product development is less ambitious, and costs less, lower barriers of entry to the marketplace will exist and the Committee expects more PMA approvals and shorter periods of data protection, a result that should not inhibit product development anymore than existing market forces. Notwithstanding the period of time it takes for the approval of four PMAs for a kind of device, the applicant for the fourth approved device will receive one year of data protection to provide some competitive advantage over future competitors.

The Committee realizes the importance of the definition of "a kind of device." The Secretary's exercise of discretion in determining whether four devices are within "a kind of device" must consider whether the devices incorporate the same technologies and principles of operation, and have the same intended uses.

The Committee intends that devices that incorporate technologies and principles of operation that are not significantly different be considered to be within the same kind of device. Device features such as design, materials, energy source, function, and other similar features that relate to the safe and effective performance of a device are probative of whether a group of devices have the same technologies and principles of operation. Also, devices of a kind must have the same intended use or uses. The Committee intends that what constitutes an intended use will be determined by the Secretary in the context of a device's approval and minor variations in a device's indication statement will not provide a means of circumventing the purpose of section 12, which is to make PMA information available to the Secretary.

The publication requirement of section 12 is intended to provide all interested persons notice that the Secretary has determined that the prerequisites for using PMA information have been met and the information will be available for the Secretary's use one year from the date of the Federal Register publication. Application holders will have the opportunity to challenge administratively the Secretary's determination. However, challenges alleging differences in technologies, principles of operation, or indications for use that are insubstantial will not overcome the Secretary's determination that a fourth device of a kind has been approved and PMA information will be available for uses specified in section 12.

Section 12 will have a retroactive effect for all devices where a fourth device of a kind was approved on or before December 31, 1987. For devices, where the original application of the fourth device of a kind was approved after December 31, 1987, the effective date of the section will be the date occurring 24 months after the enactment date of the section. The delayed effective date represents the Committee's sensitivity to changing the rules of the game regarding the degree of protection of PMA information conferred under the Amendments to PMA holders.

The Committee acknowledges that line-drawing of any sort is imperfect; however, by selecting December 31, 1987 as the cutoff date for retroactivity and establishing a two year delayed effective date, the Committee has attempted to be as fair as possible. For the four devices of a kind approved on or before December 31, 1987, each PMA holder will have had, at a minimum, approximately four years of protection for information in their PMAs. For devices where the original application of the fourth device of a kind is approved after December 31, 1987, the maximum period of PMA information protection will be approximately six years and the minimum period of protection will be two years.

The term "approval date" is defined to avoid any dispute regarding the date in which a device is approved. In all instances except one, the approval date, for purposes of this section, will be the date of the Secretary's letter approving the device and permitting an applicant to commercially distribute it. The one exception relates to the approval of a fourth device of a kind where that approval occurred between January 1, 1988 and the delayed effective date. To accommodate the notice provision of section 12, the approval date of such a device shall be deemed to be the same date as the delayed effective date of the provision.

Once the Secretary determines that the statutory prerequisites for disclosures have been met, all information in PMAs of the first four devices of a kind, and contained in all supplements thereto, excluding descriptions of methods of manufacture and product composition, and similar information from all subsequent PMAs and PMA supplements, will be available for the Secretary's use. Although the Secretary may not publicly disclose the non-public portions of the PMAs and PMA supplements available for the Secretary's use, the Secretary may use the detailed summaries of information respecting safety and effectiveness, required under section 520(h)(1)(A), as the evidentiary basis for reclassifying or approving devices, or for establishing a performance standard.

SECTION 13. TRACEABILITY

The Committee encourages the Secretary to take full advantage of the opportunity to require a tracing requirement for those device groups specified in section 13. Moreover, the Secretary has full discretion in determining by regulation the means by which devices will be traced to their ultimate users. This requirement is limited to devices with the potential for causing the greatest harm and for which the potential of a recall is greatest. The Committee is of the view that the ability to trace a device quickly is the key to a successful recall.

The Committee defines the term "ultimate user" to mean the person for whose benefit the device is intended, the patient. Where the device is one that remains in a hospital, and no adverse health consequences could befall a person subjected to it once the exposure to the device has been discontinued, the ultimate user of the device shall be deemed to be the hospital. However, where, for example, a diagnostic device is defective, such that it fails to accurately diagnose a condition, notwithstanding the fact that the device remains in a hospital, the "ultimate user" will, nonetheless, be the patient.

For purposes of this section and section 17 (postmarket surveillance) the Committee does not intend the term permanent implant to include any device which is intended and used for temporary purposes and is to be explanted.

SECTION 14. TRANSITIONAL DEVICES

This section provides a badly needed mechanism for revising the classification of the so-called transitional devices, devices regulated as new drugs prior to 1976 that were automatically placed in Class III upon passage of the Amendments. The intent of the legislation is that the Secretary will evaluate each of the transitional devices in the light of the detailed definitions provided in section 513(a) of the Act for Class I, II, and III devices. The decision as to the appropriate classification for each of these device does not meet the Class III definition, it should not be retained in Class III.

Presently, review of PMAs for transitional devices consumes a significant amount of FDA's premarket review resources. For example, approximately 50 percent of PMAs reviewed by FDA in a typical year relate to contact lense products. The Committee believes that a portion of these resources could better be spent on more pressing public health concerns.

The bill specifically states that non-hydrophilic plastic contact lenses are not to be retained in Class III unless evidence is presented showing that they meet the legal definition, contained in section 513(a)(1)(C)(ii) of the Act. Such evidence must be published in the Federal Register. Otherwise, these devices are to be assigned to either Class I or Class II. If the Secretary does not take action on nonhydrophylic plastic contact lenses within one year, they are automatically to be assigned to Class II.

There are about 20 types of transitional devices. The Committee expects that the Secretary will take complete advantage of this opportunity to revise classifications, where appropriate, to allow the redeployment of scarce agency resources to important public health issues. The Committee is aware that a number of reclassification petitions regarding transitional devices are pending before FDA. Nothing in this legislation is intended to interfere with the timely completion of action on these petitions, and the Committee expects the agency promptly to complete action on these petitions.

SECTION 15. SUBSTANTIAL EQUIVALENCE

The Committee believes that it is important to codify the Secretary's interpretation of the terms "substantial equivalence" and "substantially equivalent." The FDA's premarket notification program has become the major gateway to the market for devices, and it is critical to the agency's ability to manage a large volume of submissions that number in excess of 5,000 submissions per year. The premarket notification program is a classification program that essentially compares a post-Amendments device to a so-called pre-Amendments predicate device. If the "new" device is substantially equivalent to its predicate device then it is placed in the same class, and will be subject to the same degree of regulation as the predicate device.

Generally speaking, a device is substantially equivalent to its predicate device if it has the same intended use, and is as safe and effective, as the predicate device. The determination of comparable safety and effectiveness is at times easy, where the newer device and its predicate use the same technologies. More difficult judgments occur when the technologies of the devices differ. In this latter situation, the FDA will not make a substantial equivalance determination without data, including clinical data, that demonstrates comparable safety and effectiveness. However, notwithstanding data that may demonstrate comparable performance, the agency will not find a device substantially equivalent to a predicate device where the newer device raises different safety or effectiveness considerations than the predicate device. Under these circumstances, a finding of not substantially equivalent is made, necesstating a Class III designation and the requirement of an approved PMA before the new device may be marketed.

The Committee intends to incorporate the agency's thinking into the determination of when a newer device is considered to be as safe and effective as a predicate device. Moreover, the Committee explicitly accepts FDA's interpretation that devices with the same intended uses may be substantially equivalent, notwithstanding differing technologies. The agency's practice of requesting data is now expressly included in the statute. The Committee will leave to the Secretary's expertise and discretion the determination of how much data may be received in a premarket notification before it should be moved onto a premarket approval track. Importantly, this issue will become less signficant when pre-Amendments Class III devices, and those which are substantially equivalent to them, are subject to regulations requiring PMAs.

The Committee will now permit the Secretary to compare a newer device to any marketed device for the purpose of making a substantial equivalence determination. Also, the Commtitee is explicitly precluding comparisons of newer devices to devices removed from the market by court order or at the Secretary's intiative. It is the Committee's view that requiring comparisons of newer devices to legally and currently marketed devices will improve the overall safety and effectiveness of devices that reach the market through the FDA's premarket notification program.

SECTION 16. HUMANITARIAN DEVICE EXEMPTION

The Committee is aware that the Supreme Court in *United States* v. *Rutherford,* 442 U.S. 544 (1979) held that drugs intended for terminally ill cancer patients were not exempt from the requirements of the Act. However, the circumstances addressed by the Court in *Rutherford,* protecting patients from questionable, untested, and expensive treatments, do not address the situation covered by section 16.

The section, although providing the basis for an exemption from the Act's effectiveness requirements, nonetheless, maintains the need to establish a device's safety, and considers the factors identified in section 513(a)(2) of the Act for determining device safety and effectiveness. Specifically, the section, as a condition for an exemption, considers the persons for whose benefit the device is intended and requires an assessment of the device's risks and probable benefits. Indeed, the section's risk/benefit assessment includes a comparative assessment between the device and currently available devices and alternative forms of treatment. Additionally, an exempt device may only be used after a local institutional review committee approves the device for the treatment or diagnosis of a specific rare disease or condition.

The exemption will cover devices intended for limited populations in the United States of 8,000 or less, and the determination of the numbers of patients with a specific disease or condition will be made at the time of an application requesting the exemption. Devices intended either for groups of people numbering 8,000 or less with a specific disease, or a subset of people with a condition related to a disease, notwithstanding the fact that persons with the disease may number more than 8,000, will be eligible for an exemption, at the discretion of the Secretary.

SECTION 17. POSTMARKET SURVEILLANCE

This section creates a vital "early warning system" that allows for the early identification of potential problems with medical devices within a reasonable time of their first marketing. Less than 5 percent of devices are subject to FDA's premarket review process. Such testing occurs under highly controlled conditions and it is not possible to determine all the risks that will be associated with the device's general use Moreover, for a substantial majority of devices, the FDA sees no clinical date before the device is commercially distributed.

The Committee intends this section to allow for clinical monitoring of the earliest experiences with a device once it is distributed in the general population under actual conditions of use. Postmarket surveillance of this type may have prevented some of the tragedies associated with defective products such as the Bjork/Shiley 60 degree Convexo-Concave heart valve, or the Aequitron Apnea monitor.

In order to assure that any problems, or potential problems, are identified quickly, the Committee believes that it is critical that the Secretary require manufacturers to institute postmarket surveillance required in accordance with this section as proximate in time to the initial commercial distribution of the devide as is possible.

The Committee anticipates that the regulations issued under this section will described the appropriate criteria for clinical monitoring to accomplish the section's purpose. The Committee also expects the Secretary to establish criteria for determining the qualifications of the medical centers that will conduct the postmarket surveillance.

The Committee is aware of post-approval studies that are currently conducted for certain Class III products, as well as manufacturer-initiated efforts to determine product performance. The Committee anticipates that the Secretary will promulgate regulations that may allow, under appropriate circumstances, adaptations of such existing surveillance techniques in order to conform with the requirements of this section.

SECTION 18. OFFICE OF INTERNATIONAL RELATIONS

The Committee intends that any such agreement will not in any measure compromise the safety and effectiveness of either imported or exported devices. The Committee does not expect that the Secretary will be able to use the authority of this section to engage in the approval of devices manufactured abroad for introduction into interstate commerce in the United States; however, if the Secretary is satisfied that a foreign approval of a device, meets this country's standards, then the Secretary has the discretion to accept the foreign government's action.

SECTIONS 19 AND 20. REVIEW OF MARKET APPLICATIONS FOR ARTICLES COMPRISING COMBINATIONS OF DRUGS, DEVICES, AND BIOLOGICS

The Committee is aware of the difficulty under the present law in determining the jurisdictional base for regulating products that are comprised of combinations of drugs, devices, or biologics. This provision will provide the Secretary with firm ground rules to direct products promptly to that part of the FDA responsible for reviewing the article that provides the primary mode of action of the combination product. Various persons from industry have expressed the view that a weakness in FDA's premarket review process is the determination of how to regulate combination products. This provision should assist the Secretary in avoiding delays in making that determination, and is important since more combination products are coming before the agency for premarket review, for example, devices impregnated with with biologically-active materials, medicated devices, implantable drug pumps and biological sensors, and therapeutic devices used in conjunction with drugs for the extra-corporeal treatment of diseases.

The definitions of "drug" and "device" have been slightly altered to accommodate the principle of section 20. Section 19 amends section 201(g)(1)(D) by deleting from the drug definition the words "but does not include devices or their components, parts, or accessories." By deleting this language, a product whose primary mode of action is attributable to a drug, but has a device component, may be reviewed under this Act's drug authority. Section 19 also amends section 201(h) to delete the words "any of" from the unnumbered paragraph following section 201(h)(3). Additionally, the word "primary" is substituted for the word "principal" in that same paragraph. These changes are editorial and conform the device definition to the language in section 20.

The Committee believes that the provisions of this section also address the situation in which manufacturers of novel drug delivery systems may be required to obtain drug and device approvals, notwithstanding an approved application for the drug intended for use with the device. To the extent that the drug approval belongs to a person other than the device sponsor, a difficult route to the marketplace may result if the holder of the approved new drug applicatio refuses to permit the device applicant reference rights to the safety and effectiveness data in the approved drug application. Where this occurs the device manufacturer currently is required to pass two distinct regulatory clearance barriers. Section 20 will eliminate the need to receive clearances from both the device and drug review divisions, and will vest authority in one agency group to conduct a premarket review.

This administrative relief, however, will not eliminate the requirement to produce safety and effectiveness data for the device and drug components of the combination product, if data from the approved new drug application is not available to the device sponsor. Because the Committee is concerned that this situation has occurred, and may create barriers to the introduction of new, worthwhile devices onto the marketplace, we request that FDA reconsider the existing new drug review process. The agency should, within its administrative discretion, streamline that process to reduce the burdens described herein, where a drug delivery system is not critical to the drug's safe and effective use.

SECTION 21. MARKET EXCLUSIVITY

During the period of time between March 29, 1982 and October 31, 1988 the FDA was involved in a number of time-consuming internal and external examinations of anti-inflammation, non-steroidal drugs. Because of these examinations, the FDA review time for those drugs extended in excess of the average review time prior to 1982 of approximately two years. As a consequence, drugs about which no safety or effectiveness questions were raised were denied their expected market protection. This provision corrects the above-described situation by restoring the market exclusivity denied to any non-steroidal anti-inflammatory drug for which an application has been submitted to FDA during the specified time period.

SECTION 22. NON-PROFIT ORGANIZATION PATENT CLAIM EXTENSION

This provision is intended to allow for extensions of patents which cover more than one product, or methods of using or manufacturing more than one product. The scope of the provision is limited to those patents arising from work conducted at non-profit organizations.

V. COST ESTIMATE

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, September 28, 1990.

Hon. EDWARD M. KENNEDY,
Chairman, Committee on Labor and Human Resources,
U.S. Senate, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the attached cost estimate for S. 3006, the Comprehensive Medical Device Improvement Act of 1990, as ordered reported by the Senate Committee on Labor and Human Resources on September 26, 1990.

If you wish further details on this estimate, we will be pleased to provide them.

Sincerely,

ROBERT D. REISCHAUER,
Director.

CONGRESSTIONAL BUDGET OFFICE COST ESTIMATE

1. Bill number: S. 3006.
2. Bill title: Comprehensive Medical Device Improvement Act of 1990
3. Bill status: As ordered reported by the Senate Committee on Labor and Human Resources on September 26, 1990.
4. Bill purpose: To amend the Federal Food, Drug, and Cosmetic Act to make improvements in the regulation of medical devices, and for other purposes.
5. Estimated cost to the Federal Government:

[By fiscal years, in millions of dollars]

	1991	1992	1993	1994	1995
Estimated authorization levels:					
User reporting system	(1)	2	2	2	2
Education and information	1	1	1	—	—
HHS study	—	—	(1)	—	—
Removal and correction reports	(1)	1	1	1	1
Premarket approval	1	1	1	2	2
Office of international relations	(1)	(1)	(1)	(1)	(1)
Total estimated authorization levels	3	6	6	5	5
Total estimated outlays	3	5	6	5	5

[1] Less than $500,000.

Details in the table may not add to totals because of rounding. The costs of this bill fall within budget function 550.

Basis of Estimate: Authorization levels were not stated in the bill and thus were estimated by CBO. This estimate assumes that all authorizations are fully appropriated at the beginning of each fiscal year. Outlays are estimated using spendout rates computed by CBO on the basis of recent program data.

User Reporting System: S. 3006 would require hospitals, ambulatory surgical facilities, and nursing homes to report serious problems with medical devices to the Food and Drug Administration

(FDA). When one of these facilities has information that reasonably suggests that a medical device may have caused a patient's death, the facility must report the information to the FDA, and to the manufacturer, if known. In addition, the bill would require facilities to report cases to the FDA where a medical device may have caused a serious illness, if the manufacturer's identity is unknown.

A mandatory device reporting (MDR) system currently exists requiring manufacturers to report deaths (as they learn of them) and serious injuries (quarterly) to the FDA. Manufacturers would still be required to report under the MDR rules to the FDA. In addition, medical device distributors would also be required to submit annual statements certifying that they filed their reports.

Estimates of the cost of the user reporting system are very uncertain. Little information is available on the number of deaths and serious injuries caused each year by medical devices. The General Accounting Office (GAO) studied FDA's medical device system in 1987, surveying over 2,000 hospitals on problems associated with 10 different medical devices. They found that 46 percent of the problems identified by these hospitals were reported to the manufacturer. In recent years, manufacturers have reported about 18,000 deaths and illnesses a year to the MDR system. Using these figures, we estimate that FDA could expect to receive about 40,000 reports a year, if reporting is mandatory. This estimate incorporated duplicate reporting on the part of health facilities and manufacturers in cases where medical devices cause death, as both must then report to the FDA. It also includes the increase caused by quarterly reports from distributors required under the bill.

To accommodate a larger increase in reporting, we estimate FDA would need an additional 35 full-time-equivalent (FTE) positions. Thirty-five additional FTEs would costs approximately $2 million in fiscal years 1992 to 1994, assuming that final regugulations are enacted at the beginning of fiscal year 1992. Start-up funds would be needed in fiscal year 1991 to write preliminary and final regulatins. CBO estimates that it would cost less than $500,000 in fiscal year 1991 to enact the necessary regulations.

Education and Information: The bill would authorize the Secretary of Health and Human Services (HHS) to establish public education programs to teach health facilities about the user reporting system. The education programs are authorized at such sums as may be necessary levels for fiscal years 1991 to 1993. Based on similar education programs funded by the federal government, CBO estimates that this provision would cost $1 million in each of fiscal years 1991 to 1993.

HHS Study: S. 3006 would require the Secretary of HHS to study and submit a report 36 months after the enactment of this bill on the safety benefits and the cost-effectiveness of the user reporting system. CBO estimates that this study would cost less than $500,000 in 1993.

Removal and Correction Reports: Manufacturers would be required to report removals and field repairs of medical devices undertaken by manufacturers if done to eliminate a health risk posed by the device. Based on information provided by FDA, CBO estimates that FDA would receive about 800 reports pertaining to removal and repair of devices, and that it would cost about $1 million each fiscal year to track these reports. CBO assumes that final regulations pertaining to this provision would be enacted by the beginning of fiscal year 1992. CBO estimates that it would cost less than $500,000 in fiscal year 1991 to enact the regulation.

Premarket Approval: The FDA would be required to determine if certain devices are substantially equivalent to a device that FDA has already given premarket approval. The manufacturers would be required to prepare a summary of clinical data regarding the safety and effectiveness of the equivalent device. The FDA would review and submit these summaries for public release. Based on information provided by FDA, CBO estimates that FDA would receive about 225 summaries annually, after the enactment of final regulations in fiscal year 1992. Five additional FTEs would be required for their review.

Certain medical devices that have not undergone premarket approval would have their classification status reviewed and possibly revised. The manufacturers would be required to submit additional safety and effectiveness information not previously provided. The Secretary of HHS would be required to review this information and publish any classification change. Based on information provided by FDA, we estimate that 10 additional FTEs would be required each year to review the information.

A similar provision requires reclassification of certain transitional devices, but the process must take place within one year of enactment. Based on information provided by FDA, CBO estimates that this provision would cost about $1 million in fiscal year 1991.

Office of International Relations: The bill would authorize the Secretary of HHS to establish an Office of International Relations to plan and initiate agreements with foreign governments specifying that medical devices of either country are manufactured in a manner so that the devices are suitable for commercial distribution. Funds for salary and overhead for a director and additional staff would be needed. We estimate that the costs for a director and two additional staff would be less than $500,000 in each of fiscal years 1991 to 1995.

6. Estimated cost to State and local government: None.
7. Estimate comparison: None.
8. Previous CBO estimate: None.
9. Estimate prepared by: Karen Graham.
10. Estimate approved by: C.G. Nuckols (for James L. Blum, Assistant Director for Budget Analysis).

VI. REGULATORY IMPACT STATEMENT

The Committee has determined that there will be minimal increase in the regulatory burden as a direct result of this bill. The bill strikes a balance between the cost of protecting consumers and the reduction of costs of compliance with the law by eliminating unnecessary regulatory requirements. Although the bill will increase the amount of device adverse experience reporting to the Secretary, and require the promulgation of a number of regulations, nonetheless, several of the bill's provisions will decrease the FDA's and industry's regulatory load. These and other provisions

will avoid over-regulation of the device industry, by: (1) streamling FDA's regulatory processes; (2) redefining, where appropriate, the classification of devives presently subject to the maximum level of regulatory oversight; (3) avoiding repetitive submissions from industry; and (4) permitting the FDA access to previously protected data, thus allowing the agency to fine tune the regulatory requirements of device classification.

VII. SECTION-BY-SECTION ANALYSIS

SECTION 1. SHORT TITLE

Section 1 provides that this Act may be cited as the "Comprehensive Medical Device Improvement Act of 1990."

SECTION 2. REFERENCES TO ACT

Section 2 provides that except as otherwise specified, references are to provisions of the Federal Food, Drug, and Cosmetic Act.

SECTION 3. REVIEW OF SAFETY AND EFFECTIVENESS DATA

Section 3 amends section 510(k) and requires all persons seeking a determination that a device is substantially equivalent to a pre-Amendments Class III device, for which no final regulation requiring premarket approval has been promulgated, to conduct a reasonable search of published and unpublished data concerning the safety and effectiveness of the marketed device and the device for which a claim of substantial equivalence is made. The applicant must include in the premarket notification a certification that the search and review was conducted and a citation to and summary of the data, including, all adverse safety and effectiveness data resulting from the search. The Secretary may require the submission of the clinical and non-clinical data identified in the summary.

SECTION 4. CLASSIFICATION OF DEVICES

Section 4 amends section 513, redefines a class II device, and provides the Secretary with new mechanisms to classify devices for which general controls such as labeling are insufficient to provide reasonable assurances of safety and effectiveness. Performance standards will no longer exclusively be the control that defines devices which neither fit within the Class I nor Class III definitions. The Secretary may utilize "additional controls," such as guidelines, recommendations, or postmarket surveillance, in lieu of performance standards, to provide the requisite assurance of the safety and effectiveness of a Class II device.

This section specifically provides the Secretary with the authority to use more than one "additional control" to regulate a device. For example a device defined as a Class II product may be required to meet a performance standard as well as conduct postmarket surveillance. However, the section requires that in the case of devices represented to be for use in supporting or sustaining human life, sufficient information must exist to identify and describe a performance standard that could reasonably assure the safety and effectiveness of a device.

The Secretary is also given explicit authority to initiate the reclassification of a Class III device under section 513(f)(2) of the Act. Additionally, section 513(f)(1) of the Act is amended to make explicit the current law that findings of substantial equivalence are made by an order.

SECTION 5. REVISION OF CLASSIFICATION FOR CERTAIN CLASS III DEVICES

This section revises section 513 of the Act and establishes an orderly process requiring FDA to evaluate the so-called "grandfathered" pre-Amendments Class III devices for which no regulation under section 515(b) has been issued. Within 3 years of enactment of the legislation, the Secretary shall, by order, require every manufacturer of such a device to submit a summary of, and a citation to, all published and unpublished data concerning the safety and effectiveness data. If necessary the Secretary may require a manufacturer to submit any data described in the summary.

Based upon the information contained in the summaries, the Secretary must, within 2 years of the initial order, issue a proposed regulation for each device covered by the order either to retain the device in Class III or downclassify the device in Class II or Class I. In a final regulation, not to be published until at least 90 days after the proposed regulation, the Secretary shall continue the classification of the device in Class III or change its Class II or I. Within not more than one year after the effective date on a final regulation, the Secretary is required to establish a schedule for the promulgation of regulations in accordance with section 515(b), requiring PMAs for each device that has been retained in Class III.

SECTION 6. PERFORMANCE STANDARDS

Section 6 amends section 514 of the act by simplifying the procedures for establishing or revoking performance standards. This section dispenses with the extremely complex procedures of current law and replaces them with a simple notice and comment rulemaking proceeding. In addition, this section specifices that performance standards are no longer mandatory for all Class II devices, but may be established at the discretion of the Secretary.

SECTION 7. SUSPENSION OF APPROVAL OF APPLICATION

Section 7 amends section 515(e) of the Act to include new paragraphs (3)(A) through (D). These paragraphs describe the means by which the Secretary may by order suspend the approval of a premarket application for a device where the Secretary determines that there is a reasonable probability that the continued distribution of a device would cause serious, adverse health consequences or death. Essentially, the Secretary must give the application holder 10 days notice of an opportunity for an informal hearing to determine whether to issue the order. Thereafter, the Secretary must either issue an order suspending the application approval or determine that such an order is improper. If the Secretary issues an order to suspend a device approval, he must initiate the process to withdraw the application within 20 days of the suspension order or it will be vacated by operation of law.

SECTION 8. JUDICIAL REVIEW

This section amends section 517 of the Act by referencing the administrative proceedings described in S. 3006 that will be reviewable in the United States Court of Appeals. Any challenge to the Secretary's revision of classification of pre-Amendments Class III devices, and those that are substantially equivalent to such devices, will be heard in the United States Court of Appeals for the District of Columbia or the circuit wherein such person resides or has his principal place of business. Likewise, any order determining whether a product is substantially equivalent or not substantially equivalent to a market device will be heard in the United States Court of Appeals.

SECTION 9. EMERGENCY RECALL AUTHORITY

Section 9 adds a new section 518(e) to the Act providing the FDA explicit authority, to order the immediate cessation of the distribution of a device and, thereafter, its recall from commercial distribution and use, whenever the Secretary finds there is reasonable probability that a device will cause serious adverse health consequences or death.

After the issuance of the recall order, the party to whom the order is directed is given the opportunity for an informal hearing within 10 days. If, after providing this opportunity for an informal hearing, the Secretary determines that the recall is proper, the Secretary shall specify a timetable and require the manufacturer, importer, distributor, or retailer subject to the order to report periodically on the progress of the recall.

The party subject to a recall order must (1) remedy the causes that led to the recall order, (2) complete the recall in accordance with the recall order, and (3) submit a report to the Secretary demonstrating the party's compliance with the order. The party may then petition the Secretary to vacate the recall order, which may only be vacated if the three requirements cited above are met, and it has been established that the device may once again be distributed in interstate commerce. The Secretary must respond to a petition to vacate a recall order within 30 days of its receipt.

The emergency recall authority is in addition to other remedies in section 518 of the Act, including patient notification under subsection 518(a).

SECTION 10. USER REPORTS

This section, which amends section 519 of the Act, requires facilities which use medical devices, defined as hospitals, nursing homes, or ambulatory surgical facilities, to submit reports if there is a reasonable suggestion that the device has caused or contributed to the death of a patient of the facility or if there is a reasonable suggestion that the device has caused or contributed to the serious illness or injury of one of the facility's patients. A serious illness or injury is defined as any unanticipated illness or injury which is life threatening, which results in permanent impairment or permanent damage to a body structure, or which requires immediate medical intervention to prevent permanent bodily impairment or damage.

When a medical device user facility becomes aware of information that reasonably suggests a device-related death, the facility is require to report the death to the Secretary as soon as practicable, but not later than 15 working days after it becomes aware of the information. In addition, the facility is to report the information to the manufacturer of the device if the identity of the manufacturer is known.

The bill states that facilities only have the duty to make reports under this section whenever appropriate medical personnel of the facility become aware of device-related events, in the course of their duties, that would give rise to a report.

When a medical device user facility becomes aware of information that reasonably suggests a device-related serious illness or injury, the facility is required to report the serious illness or injury to the manufacturer as soon as practicable, but not later than 15 working days after becoming aware of the information. For serious illness or injury reports, the section provides that if the facility is unable to determine the identity of the manufacturer, the report should be sent to the Secretary.

The bill provides that the Secretary is prohibited, except in rare circumstances, from disclosing the identity of a facility making reports under this section. The bill also provides that reports made in accordance with this section may not be admitted into evidence in any civil action, unless the person submitting the report was aware of its falsity.

The bill clarifies that the obligation of medical device user facilities to make reports in accordance with this section shall not affect the obligations of manufacturers to file reports in compliance with the MDR regulation established to implement section 519(a) of the Act.

The section requires the Secretary to promulgate a regulation, within one year of its enactment, implementing the new user reporting requirements. The reporting requirements of this section shall become effective either upon the effective date of the regulation or 12 months after enactment of this legislation, whichever occurs first.

Section 10 requires the Secretary, not later than one year after the enactment date of the section, to promulgate regulations requiring distributors of medical devices to meet the reporting obligations of section 519(a) of the Act, but provides that the Secretary may exempt classes of distributors if their inclusion in the regulation is not necessary to protect the public health. The bill also requires each manufacturer, importer, and distributor, making reports under this section, to submit an annual report to the Secretary certifying either that no MDR reports were filed in the preceding year, or that a certain number of reports were filed.

The Secretary also is given authority to award grants to medical device user facilities to establish education programs concerning the reporting requirements of this section. And not later than three years after the enactment of this legislation, the Secretary is required to submit a report to the appropriate committees of Congress evaluating the reporting requirements of this section.

SECTION 11. REPORTS OF REMOVALS AND CORRECTIVE ACTIONS

Section 11 amends section 519 of the Act by directing the Secretary to promulgate regulations requiring the prompt reporting of device removals or corrective actions undertaken to eliminate significant risks to health, or to remedy violations of the Act which may present risks to health, caused by the device. Reports of corrective actions or removals will not be required under this section where a report or corrective action is already required by the Act. This section also will not require reports or removals of corrective actions if the action is undertaken at the request of the Secretary and a report has already been submitted to the agency. Where removals or corrective actions of devices do not require a report under this section, the person who implements the removal or corrective action, including the manufacturer, importer, or distributor, must keep a record of the action taken. Routine servicing is expressly excluded as an act that may give rise to a report or the keeping of a record described in the section.

SECTION 12. USE OF PREMARKET APPROVAL DATA

This section amends section 520(h) of the Act to add new paragraph (4) which permits the Secretary the use of certain safety and effectiveness information from premarket approval applications to approve PMAs, determine whether a product development protocol has been completed, establish a performance standard, or reclassify a device. Data from premarket approval applications will be available for the Secretary's use one year after the approval of the original application of a fourth device of a kind. All information within the application, excluding descriptions of methods of manufacture and product composition, and including clinical and preclinical tests or studies, may be used by the Secretary, as specified in the bill. However, prior to using the PMA information, the Secretary must publish in the Federal Register the identity of the four devices of a kind and the date on which the information contained in the PMAs will be available for the Secretary's use. In all instances, the PMA information will not be available to the Secretary until one year after the date of the Federal Register publication. In pursuing any administrative action specified in section 12, the Secretary may use the detailed summaries of safety and effectiveness, required to accompany each device approval, as the evidentiary basis for the Secretary's determination.

The section also identifies the characteristics that define a "kind of device" The Secretary shall deem devices with the same technologies and principles of operation, and are intended for the same intended use or uses, to be within a "kind of device."

The effective date of the section varies depending on a device's approval date. For devices, where the fourth of a kind was approved on or before December 31, 1987, the section shall become effective upon its enactment date. For devices in which fourth of a kind was not approved on or prior to December 31, 1987, the effective date will be the date twenty-four months after the section's enactment.

With one exception, the bill defines the approval date for a device to be the date of the Secretary's letter approving the device and permitting its commercial distribution. Where the original application of the fourth device of a kind is approved on or after January 1, 1988, and before the delayed effective date, the approval date is deemed to be the delayed effective date.

SECTION 13. TRACEABILITY

This section replaces section 520(j) of the Act and requires the Secretary to determine, not later than one year after the bill's enactment date, from among those devices that are permanent implants, purported or represented to be for use in supporting or sustaining human life, or present a potential unreasonable risk of illness or injury, which devices should be subject to a requirement of labeling, coding, or identification by any other means to ensure that a device may be traced from its place of manufacture or initial distribution to the device's ultimate user. Not later than two years after the enactment date, the Secretary shall promulgate a regulation to require manufacturers, importers, and distributors of such devices to establish by which a device can be traced to its ultimate user.

SECTION 14. TRANSITIONAL DEVICES.

This section amends section 520(l) of the Act and requires the Secretary to publish in the Federal Register, within 90 days of the section's enactment date, a notice identifying each transitional device the Secretary intends to keep in Class III or to classify into Class I or Class II. The notice will require, for each such device the Secretary intends to classify into Class I or Class II, the submission of a description and citation to any adverse safety and effectiveness information submitted under section 519(a) of the present Act. The Secretary has the discretion to require the submission of the safety and effectiveness information for which a description and citation have been submitted to FDA.

After issuance of the notice order, but within the first year after the section's enactment date, the Secretary shall publish a proposed regulation in the Federal Register regarding all transitional devices either retaining their Class III classification or revising, where appropriate, their classification into Class II or Class I. The evidentiary basis to support the revision of classification will be the adverse safety and effectiveness data furnished to FDA and the advice and recommendations of appropriate advisory panels. Within one year of the section's enactment date, but not earlier than 90 days after its publication, the Secretary shall promulgate a final regulation. The section provides the Secretary discretion to extend the regulation process by one year, by publishing a notice in the Federal Register alerting interested persons of the section's extended timetable.

The section states that nonhydrophilic plastic contact lenses are not to be retained in Class III unless evidence is presented showing that they meet the legal definition contained in Section 513(a)(1)(C)(ii) of the present law. Such evidence must be published in the Federal Register. Otherwise, these devices are to be assigned to either Class I or Class II. If the Secretary has not completed action on nonhydrophilic plastic contact lenses within one year, they are to be assigned to Class II.

Finally, the bill identifies those transitional devices ineligible for revision of classification under this section. Transitional devices for which reclassification petitions are pending as of January 1, 1989, will not be considered under this section's one-time opportunity for classification revision.

SECTION 15. SUBSTANTIAL EQUIVALENCE

Section 15 amends the Act by adding a new section 520(m) which is intended to codify the Secretary's interpretation of the term "substantialy equivalent" as used in the Act, including sections 513, 515, and 520. Section 15 defines "substantially equivalent" and "substantial equivalence" to mean two devices, a newer device and a marketed device, that have the same intended uses and are comparably safe and effective.

The section provides that information, including clinical data, may be required to determine the comparable safety and effectiveness between a device and its predicate. Section 15 precludes a comparison between a device and a marketed or predicate device where the predicate device has been removed from the market either because it was found to be misbranded or adulterated by a court or its was removed from commercial distribution at the Secretary's initiative. The section also provides that the Secretary shall promulgate regulations which will prescribe a standard format for a summary of clinical data submitted in a premarket notification. The regulation may require persons seeking substantial equivalence determinations to prepare and submit summaries of the clinical data to the Secretary, which shall be made public by the Secretary within 30 days of a substantial equivalence determination.

SECTION 16. HUMANITARIAN DEVICE EXEMPTION

Section 16 amends the Act by including a new section 520(n) which exempts devices intended for use in the treatment or diagnosis of rare diseases or conditions from the effectiveness requirements of the Act. Rare diseases or conditions are defined as diseases or conditions that affect fewer than 8,000 persons in the United States. The section's purpose is to encourage the discovery of devices that are intended to benefit persons with rare diseases and requires the Secretary to promulgate regulations within 8 months of its enactment date prescribing the procedures and conditions under which a device may be exempt from the Act's effectiveness requirement.

A device may only be exempt from showings of effectiveness where it is likely to provide a significant benefit to a patient in the treatment or diagnosis of a disease, or significantly benefit the patient's quality of life. Also, to qualify for an exemption, a device cannot reasonably be expected to be available, or its effectiveness be feasibly evaluated in a clinical trial, due to limited numbers of patients who would benefit from its use. Additionally, the Secretary must determine that the probable benefit from the use of the device outweighs the risk of illness or injury associated with its use, and that the risk/benefit assessment of the device is more favorable than the risk/benefit ratio of currently available devices or alternative forms of treatment. Exempt humanitarian devices may only be used at facilities with institutional review committees, established in accordance with the Secretary's regulations, that approve the use of the device in the treatment or diagnosis of a specific rare disease or condition.

SECTION 17. POSTMARKET SURVEILLANCE

Section 17 adds a new section 522 to the Act concerning postmarket surveillance. It requires the Secretary to order postmarket surveillance for each device contained within the following types of devices: permanent implants the failure of which may cause serious, adverse health consequences or death, devices intended for use in supporting or sustaining human life, or devices presenting the potential for serious risk to human health. The Secretary is given discretion to require postmarket surveillance of any device if the Secretary determines that such surveillance is necessary to protect the public health or to evaluate the safety or effectiveness of the device.

This section mandates that manufacturers of devices, for which postmarket surveillance is required, contract with a qualified academic medical center or centers to conduct monitoring of clinical experience. However, if an academic medical center with the qualification and experience necessary to conduct adequate monitoring of clinical experience is not available, the manufacturer is allowed to contract with a qualified medical centers. Manufacturers are required to obtain the approval of the Secretary concerning the number and identity of the centers that will perform surveillance in accordance with this section.

The Secretary is instructed to issue regulations implementing the requirements of this section within one year of the enactment date of this bill; however, the requirements of this section shall only apply to those devices distributed in interstate commerce after the enactment date of this provision.

SECTION 18. OFFICE OF INTERNATIONAL RELATIONS

This section provides the Secretary with the authority to enter into agreements with foreign governments to promote uniform regulatory requirements for devices. The section encourages the Secretary to pursue the mutual recognition from foreign governments of good manufacturing practices and any other rules, regulations, or testing protocols deemed appropriate by the Secretary. The Secretary is instructed to establish an "Office of International Relations" that will assess the impact of any possible agreements made under the authority of this section on the competitiveness of the United States medical device industry. This section provides that the Secretary shall submit to the appropriate committeees of Congress a report on the activities of the Office of International Relations not later than two years after the enactment date of this legislation.

SECTION 19. DEFINITIONS

Section 19 alters the drug and device definitions in section 201 of the Act. Language is removed from the drug definition that will permit an approval of a drug/device combination. Changes in the device definition are editorial to make the device definition compatible with the terminology used in section 20.

SECTION 20. REVIEW OF MARKET APPLICATIONS FOR ARTICLES COMPRISING COMBINATIONS OF DRUGS, DEVICES, AND BIOLOGICS

Section 20 amends section 503 of the act and describes the general procedures for determining the appropriate component of the FDA to review premarket submissions for products that are comprised of any combination of drugs, devices, or biologicals. If the Secretary determines that the primary mode of action of the combination product is associated with drugs, devices, or biologicals, then the Secretary shall assign to the organizational unit within FDA, charged with the premarket review of the element associated with the product's primary mode of action, the responsibility to review the premarket submission of the combination product. However, the Secretary will retain the authority to use any FDA resources necessary to ensure an adequate premarket review. The section also requires the Secretary to promulgate regulations within one year of its enactment date to implement procedures for facilitating the premarket review of combination products. Section 20 also defines the terms "biological product" and "market clearance," as used within the section.

SECTION 21. MARKET EXCLUSIVITY

Section 21 of the bill addresses a situation involving FDA's review of a class of drugs, during a period of time between March 29, 1982 and October 31, 1988.

SECTION 22. NON-PROFIT ORGANIZATION PATENT CLAIM EXTENSION

This provision allows for the extension of patents covering more than one product, which arise from the work of a non-profit organization, and which relate to products that are subjected to premarket review.

VIII. VOTES IN COMMITTEE

S. 3006 was brought up for markup at the Labor and Human Resources Executive Session on September 26, 1990. At that time, Senator Dodd offered an amendment in the nature of a substitute. The bill as amended was reported favorably from the Committee by a vote of 16-0.

X. CHANGES IN EXISTING LAW

In compliance with rule XXVI paragraph 12 of the Standing Rules of the Senate, the following provides a print of the statute or the part or section thereof to be amended or replaced (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

FEDERAL FOOD, DRUG, AND COSMETIC ACT

CHAPTER I—SHORT TITLE

* * * * * * *

CHAPTER II—DEFINITIONS

SEC. 201. For the purposes of this Act—
(a)(1) * * *

* * * * * * *

(g)(1) The term "drug" means (A) articles recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any functions of the body of man or other animals; and (D) articles intended for use as a component of any articles specified in clause (A), (B), or (C)**[**; but does not include devices or their components, parts, or accessories**]**.

* * * * * * *

(h) * * *

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which does not achieve **[**any of its principal**]** *its primary* indended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

[EXEMPTIONS IN CASE OF DRUGS AND DEVICES**]** *EXEMPTIONS AND CONSIDERATION FOR CERTAIN DRUGS, DEVICES, AND BIOLOGICAL PRODUCTS*

SEC. 503. * * *

* * * * * * *

"(f)(1) The Secretary shall designate a component of the Food and Drug Administration to regulate products that constitute a combination of a drug, device, or biological product. The Secretary shall determine the primary mode of action of the combination product. If the Secretary determines that the primary mode of action is that of—

(A) a drug (other than a biological product), the persons charged with premarket review of drugs shall have primary jurisdiction;

(B) a device, the persons charged with premarket review of devices shall have primary jurisdiction; or

(C) a biological product, the persons charged with premarket review of biological products shall have primary jurisdiction.

(2) Nothing in this subsection shall prevent the Secretary from using any agency resources of the Food and Drug Administration necessary to ensure adequate review of the safety, effectiveness, or substantial equivalence of an article.

(3) The Secretary shall promulgate regulations to implement market approval procedures in accordance with paragraphs (1) and (2) not later than 1 year after the date of enactment of this subsection.

(4) As used in this subsection:

(A) The term "biological product" has the meaning given the term in section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)).

(B) The term "market clearance" includes—

(i) approval of an application under section 505, 507, 515, or 520(g);

(ii) a finding of substantial equivalence under this subchapter; and

(iii) approval of a product or establishment license under subsection (a) or (d) of section 351 of the Public Health Service Act (42 U.S.C. 262).

* * * * * * *

NEW DRUGS

SEC. 505. (a) * * *

* * * * * * *

(8) The Secretary may not approve an abbreviated application for new drug approval under this subsection for a period of 10 years from the date of the approval of the listed drug, if the listed drug—

(A) is an anti-inflammatory, non-steroidal drug; and

(B) is a drug for which an application under subsection (b) was submitted on or before March 29, 1982, and approved on or after October 31, 1988.

* * * * * * *

REGISTRATION OF PRODUCERS OF DRUGS AND DEVICES

SEC. 510. (a) * * *

* * * * * * *

(k)*(1)* Each person who is required to register under this section and who proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use shall, at least ninety days before making such introduction or delivery, report to the Secretary (in such form and manner as the Secretary shall by regulation prescribe)—

[(1)**]** *(A)* the class in which the device is classified under section 513 or if such person determines that the device is not classified under such section, a statement of that determination and the basis for such person's determination that the device is or is not so classified, and

[(2)**]** *(B)* action taken by such person to comply with requirements under section 514 or 515 which are applicable to the device.

(2)(A) The requirements of subparagraph (B) shall apply to a person who submits a notification in accordance with paragraph (1)

for a device that the person claims is substantially equivalent to a marketed device—

(i) that was introduced or delivered for introduction into interstate commerce for commercial distribution before the date of enactment of this paragraph;

(ii) that is classified as a class III device in accordance with subsections (b) through (d) of section 513; and

(iii) for which no final regulation requiring premarket approval has been promulgated in accordance with section 515(b).

(B) A person described in subparagraph (A) shall—

(i) prior to the submission of a notification in accordance with paragraph (1), conduct a reasonable search for, and review of, published and unpublished data available to the person concerning the safety and effectiveness of the marketed device and the device for which the notification is submitted, including all adverse safety and effectiveness data concerning the devices, except for data that has been submitted to the Secretary in accordance with section 519 of this Act and section 803 of title 21, Code of Federal Regulations; and

(ii) include in the notification a certification that the search and review was conducted and a citation to and summary of the data resulting from the search.

(C) The Secretary may require the submission of any data described in the summary required by paragraph (B)(ii).

* * * * * * *

CLASSIFICATION OF DEVICES INTENDED FOR HUMAN USE

Device Classes

SEC. 513(a)(1). There are established the following classes of devices intended for human use:

(A) CLASS I, GENERAL CONTROLS.—

(i) * * *

* * * * * * *

(ii) A device for which insufficient information exists to determine that the controls referred to in clause (i) are sufficient to provide reasonable assurance of the safety and effectiveness of the device [or to establish a performance standard] *or to establish an additional control or controls, as described in subparagraph (B)(ii),* to provide such assurance, but because it—

* * * * * * *

[(B) CLASS II, PERFORMANCE STANDARDS.—A device which cannot be classified as a class I device because the controls authorized by or under sections 501, 502, 510, 516, 518, 519, and 520 by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, for which there is sufficient information to establish a performance standard to provide such assurance, and for which it is therefore necessary to establish for the device a performance standard under section 514 to provide reasonable assurance of its safety and effectiveness.]

(B) CLASS II, ADDITIONAL CONTROLS.—A device—

(i) that cannot be classified as a class I device because general controls are insufficient to provide reasonable assurance of the safety and effectiveness of the device;

(ii) for which there is sufficient information to establish an additional control or controls to provide the assurance, including—

(I) promulgating a performance standard;

(II) developing and disseminating a guideline, including a guideline for the submission of clinical data in a premarket notification submission in accordance with section 510(k);

(III) requiring the use of postmarket surveillance as appropriate in accordance with section 522; and

(IV) making a recommendation or taking other appropriate action considered necessary by the Secretary to provide reasonable assurance of the safety and effectiveness of the device; and

(iii) for which it is necessary to establish an additional control or controls to provide reasonable assurance of the safety and effectiveness of the device;

except that for a device that is purported or representated to be for a use in supporting or sustaining human life, sufficient information must exist for the Secretary to identify and describe the provision of a performance standard to provide such assurance.

(C) CLASS III, PREMARKET APPROVAL.—A device which because—

(i)(I) it cannot be classified as a class I device because insufficient information exists to determine that the controls authorized by or under sections 501, 502, 510, 516, 518, 519, and 520 are sufficient to provide reasonable assurance of the safety and effectiveness of the device and (II) cannot be classified as a class II device because insufficient information exists for the [establishment of a performance standard] *establishment of an additional control, as described in subparagraph (B)(ii),* to provide reasonable assurance of its safety and effectiveness, and

* * * * * * *

Initial Classification of Certain Devices

(f)(1) Any device intended for human use which was not introduced or delivered for introduction into interstate commerce for commercial distribution before the date of the enactment of this section is classified in class III unless *the Secretary by order determines that—*

* * * * * * *

(2)(A) [The] *The Secretary may initiate the reclassification of a device classified in class III under paragraph (1), or a* manufacturer or importer of a device classified under paragraph (1) may petition the Secretary (in such form and manner as he shall prescribe) for the issuance of an order classifying the device in class I or class II.

Within thirty days of the filing of such a petition, the Secretary shall notify the petitioner of any deficiencies in the petition which prevent the Secretary from making a decision on the petition.

* * * * * * *

Revision of Classification

(h)(i) The requirements established by order in accordance with paragraph (2) shall apply with respect to a device–

(A) that was introduced or delivered for introduction into interstate commerce for commerical distribution before the date of enactment of this subsection;

(B) that is classified as a class III device; and

(C) for which no final regulation requiring premarket approval has been promulgated in accordance with section 515(b).

(2) Not later than 36 months after the date of enactment of this subsection, the Secretary—

(A) shall by order require manufacturers of devices described in pargarph (1) to submit to the Secretary a citation to and summary of all published and unpublished data reasonably available to the manufacturer concerning the safety and effectiveness of the device including any adverse safety and effectiveness data, except for information that has been submitted to the Secretary under section 519 of this Act and section 803 of title 21, Code of Federal Regulations; and

(B) may require a manufacturer to submit any data described in the summary.

(3) After the issuance of an order in accordance with paragraph (2)(A), but not later than 24 months after the issuance of the order, the Secretary shall publish in the Federal Register for each device covered by the order a notice of proposed rulemaking proposing to change the classification of the device to class II or to class I or to continue the classification of the device in class III.

(4) In determining whether to revise the classification of a device or to continue the classification of the device in class III, the Secretary shall apply the criteria in section 513(a) to the information available when the device was initially classified and any new information made available since initial classification.

(5) After considering any comments submitted in response to the notice of proposed rulemaking, the Secretary shall issue a final regulation changing the classification of the device or coninuing the classification in class III. The Secretary shall publish in the Federal Register findings on the matters referred to in paragraph (4) a discussion of the comments received in response to the notice of the proposed rulemaking, and the response of the Secretary to the comments. The Secretary shall publish the final regulation not earlier than 90 days, and not later than 12 months, after the date of publication of the notice of proposed rulemaking relating to the regulation.

(6) A regulation issued in accordance with paragraph (5) is subject to judicial review in accordance with section 517.

(7) Not later than 12 months after the effective date of any regulation issued in accordance with paragraph (5), the Secretary shall establish a schedule for the issuance of a regulation in accordance

with section 515(b) requiring submission of a premarket approval application for each device that has been continued in class III.

Definitions

[(h)] *(i)* For purposes of this section and sections 501, 510, 514, 515, 516, 519, and 520—

(1) a reference to "general controls" is a reference to the controls authorized by or under sections 501, 502, 510 *(except for a guideline for the submission of clinical data in a premarket notification submission in accordance with section 510(k))*, 516, 518, 519, and 520,

(2) a reference to "class I," "class II," or "class III" is a reference to a class of medical devices described in subparagraph (A), (B), or (C) of subsection (a)(1), and

(3) a reference to a "panel under section 513" is a reference to a panel established or authorized to be used under this section.

PERFORMANCE STANDARDS

Provisions of Standards

SEC. 514. (a)(1) [The Secretary may] *If the Secretary determines that a performance standard is necessary to provide reasonable assurance of the safety and effectiveness of a class II device, the Secretary shall* by regulation, promulgated in accordance with this section, establish a performance standard for class II device. A class III device may also be considered a class II device for purposes of establishing a standard for the device under this section if the device has been reclassified as a class II device under a regulation under section 513(e) but such regulation provides that the reclassification is not to take effect until the effective date of such a standard for the device.

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[Initiation of a Proceeding for a Performance Standard

[(b)(1) A proceeding for the development of a performance standard for a device shall be initiated by the Secretary by the publication in the Federal Register of notice of the opportunity to submit to the Secretary a request (within fifteen days of the date of the publication of the notice) for a change in the classification of the device based on new information relevant to its classification.

[(2) If, after publication of a notice pursuant to paragraph (1) the Secretary receives a request for a change in the device's classification, he shall, within sixty days of the publication of such notice and after consultation with the appropriate panel under section 513, by order published in the Federal Register, either deny the request for change in classification or give notice of his intent to initiate such a change under section 513(e).

[Invitation for Standards

[(c)(1) If, after the publication of a notice under subsection (b), no action is required under paragraph (2) of such subsection or the

Secretary denies a request to change the classification of the device with respect to which such notice was published, the Secretary shall publish in the Federal Register a notice inviting any person, including any Federal agency, to—

[(A) submit to the Secretary, within sixty days after the date of publication of the notice, an existing standard as a proposed performance standard for such device, or

[(B) offer, within sixty days after the date of publication of the notice, to develop such a proposed standard.

[(2) A notice published pursuant to paragraph (1) for an offer for the development of a proposed performance standard for a device—

[(A) shall specify a period within which the standard is to be developed, which period may be extended by the Secretary for good cause shown; and

[(B) shall include—

[(i) description or other designation of the device,

[(ii) a statement of the nature of the risk or risks associated with the use of the device and intended to be controlled by a performance standard,

[(iii) a summary of the data on which the Secretary has found a need for initiation of the proceeding to develop a performance standard, and

[(iv) identification of any existing performance standard known to the Secretary which may be relevant to the proceeding.

[(3) The Secretary shall by regulation require that an offeror of an offer to develop a proposed performance standard submit (and if the offeror is a business entity, require that appropriate directors, officers, and employees of, and consultants to, the business entity submit) to the Secretary such information concerning the offeror as the Secretary determines is relevant with respect to the offeror's qualifications to develop a proposed performance standard for a device, including information respecting the offeror's financial stability, expertise, and experience, and any potential conflicts of interest, including financial interest in the device for which the proposed standard is to be developed, current industrial or commercial affiliates of the offeror, current sources of financial support for research, and business entities in which the offeror has a financial interest, which may be relevant with respect to the offeror's qualifications. Such information submitted by an offeror may not be made public by the Secretary unless required by section 552 of title 5, United States Code, except that in the case of information submitted by an offeror whose offer has been accepted, the Secretary shall make such information (other than information which because of subsection (b)(4) of section 552, title 5, United States Code, is exempt from disclosure pursuant to subsection (a) of such section) public at the time the offer is accepted.

[(4) If the Secretary determines that a performance standard can be developed by any Federal agency (including an agency within the Department of Health, Education, and Welfare), the Secretary may—

[(A) if such determination is made with respect to an agency within such Department, develop such a standard in lieu of accepting any offer to develop such a standard pursuant to a notice published pursuant to this subsection, or

[(B) if such determination is made with respect to any other agency, authorize such agency to develop such a standard in lieu of accepting any such offer.

In making such a determination respecting a Federal agency, the Secretary shall take into account the personnel and expertise within such agency. The requirements described in subparagraphs (B) and (C) of subsection (e)(4) shall apply to development of a standard under this paragraph.

[Acceptance of Certain Existing Standards

[(d)(1) If the Secretary—

[(A) determines that a performance standard has been issued or adopted or is being developed by any Federal agency or by any other qualified entity or receives a performance standard submitted pursuant to a notice published pursuant to subsection (c), and

[(B) determines that such performance standard is based upon scientific data and information and has been subjected to scientific consideration.

he may, in lieu of accepting any offer to develop such a standard pursuant to a notice published pursuant to subsection (c), accept such standard as a proposed performance standard for such device or as a basis upon which a proposed performance standard may be developed.

[(2) If a standard is submitted to the Secretary pursuant to a notice published pursuant to subsection (c) and the Secretary does not accept such standard, he shall publish in the Federal Register notice of that fact together with the reasons therefor.

[Acceptance of Offer To Develop Standard

[(e)(1) Except as provided by subsections (c)(4) and (d), the Secretary shall accept one, and may accept more than one, offer to develop a proposed performance standard for a device pursuant to a notice published pursuant to subsection (c) if he determines that (A) the offeror is qualified to develop such a standard and is technically competent to undertake and complete the development of an appropriate performance standard within the period specified in the notice, and (B) the offeror will comply with procedures prescribed by regulations of the Secretary under paragraph (4) of this subsection. In determining the qualifications of an offeror to develop a standard, the Secretary shall take into account the offeror's financial stability, expertise, experience, and any potential conflicts of interests (including financial interest in the device for which such standard is to be developed) and other information submitted pursuant to subsection (c)(3), which may be relevant with respect to the offeror's qualifications.

[(2) The Secretary shall publish in the Federal Register the name and address of each person whose offer is accepted under paragraph (1) and a summary of the terms of such offer as accepted.

[(3) If such an offer is accepted, the Secretary may, upon application which may be made prior to the acceptance of the offer, agree to contribute to the offeror's cost in developing a proposed standard if the Secretary determines that such contribution is likely to result in a more satisfactory standard than would be developed without such contribution. The Secretary shall by regulation prescribe the items of cost in which he will participate, except that such items may not include the cost of construction (except minor remodeling) or the acquisition of land or buildings. Payments to an offeror under this paragraph may be made without regard to section 3648 of the Revised Statutes (31 U.S.C. 529).

[(4) The Secretary shall prescribe regulations governing the development of proposed standards by persons whose offers are accepted under paragraph (1). Such regulations shall, notwithstanding subsection (b)(A) of section 553 of title 5, United States Code, be promulgated in accordance with the requirements of that section for notice and opportunity for participation and shall—

[(A) require that performance standards proposed for promulgation be supported by such test data or other documents or materials as the Secretary may reasonably require to be obtained;

[(B) require that notice be given to interested persons of the opportunity to participate in the development of such performance standards and require the provision of such opportunity;

[(C) require the maintenance of records to disclose (i) the course of the development of performance standards proposed for promulgation, (ii) the comments and other information submitted by any person in connection with such development, including comments and information with respect to the need for such performance standards, and (iii) such other matters as may be relevant to the evaluation of such performance standards;

[(D) provide that the Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and other records, relevant to the expenditure of any funds contributed by the Secretary under paragraph (3); and

[(E) require the submission of such periodic reports as the Secretary may require to disclose the course of the development of performance standards proposed for promulgation.

[(5) If an offer is made pursuant to a notice published pursuant to subsection (c) and the Secretary does not accept such offer, he shall publish in the Federal Register notice of that fact together with the reasons therefor.

[Development of Standard by Secretary After Publication of Subsection (c) Notice

[(f) If the Secretary has published a notice pursuant to subsection (c) and—

[(1) no person makes an offer or submits a standard pursuant to the notice;

[(2) the Secretary has not accepted an existing performance standard under subsection (d) or accepted an offer to develop a proposed performance standard pursuant to the notice; or

[(3) the Secretary has accepted an offer or offers to develop a proposed performance standard, but determines thereafter that—

[(A) the offeror under each such offer is unwilling or unable to continue the development of the performance standard which was the subject of the offer or offers, or

[(B) the performance standard which has been developed is not satisfactory,

and publishes notice of that determination in the Federal Register together with his reasons therefor;

then the Secretary may proceed to develop a proposed performance standard. The authority provided by this subsection is in addition to the authority provided by subsection (c)(4). The requirements described in subparagraphs (B) and (C) of subsection (e)(4) shall apply to the development of a standard by the Secretary under this subsection.]

(1)(A) The Secretary shall publish in the Federal Register a notice of proposed rulemaking for the establishment, amendment, or revocation of any performance standard for a device.

(B) A notice of proposed rulemaking for the establishment or amendment of a performance standard for a device shall—

(i) set forth a finding with supporting justification that the performance standard is appropriate and necessary to provide reasonable assurance of the safety and effectiveness of the device;

(ii) set forth proposed findings with respect to the risk of illness or injury that the performance standard is intended to reduce or eliminate;

(iii) invite interested persons to submit to the Secretary within 30 days of the publication of the notice, requests for changes in the classification of the device based on new information relevant to the classification; and

(iv) invite interested persons to submit an existing performance standard for the device, including a draft or proposed performance standard, for consideration by the Secretary.

(C) A notice of proposed rulemaking for the revocation of a performance standard shall set forth a finding with supporting justification that the performance standard is no longer necessary to provide reasonable assurance of the safety and effectiveness of a device.

(D) The Secretary shall provide for a comment period of no fewer than 60 days.

(2) If, after publication of a notice in accordance with paragraph (1), the Secretary receives a request for a change in the classification of the device, the Secretary shall, within 60 days of the publication of the notice, consult with a classification panel described in the second sentence of section 513(e).

Establishment of a Standard

[(g)]*(b)*(1)(A) After publication pursuant to subsection (c) of a notice respecting a performance standard for a device, the Secretary shall either—

* * * * * * *

(3)(A) After the expiration of the period for comment on a notice of proposed rulemaking published under paragraph (1) respecting a performance standard and after consideration of such comments and any report from an advisory committee under paragraph (5), the Secretary shall (i) promulgate a regulation establishing a performance standard and publish in the Federal Register findings on the matters referred to in [paragraph (2)] *paragraph (1)*, or (ii) publish a notice terminating the proceeding for the development of the standard together with the reasons for such termination. If a notice of termination is published, the Secretary shall (unless such notice is issued because the device is a banned device under section 516) initiate a proceeding under section 513(d) to reclassify the device subject to the proceeding terminated by such notice.

* * * * * * *

(4)(A) The Secretary, upon his own initiative or upon petition of an interested person may by regulation, promulgated in accordance with the requirements of [paragraphs (2) and (3)(B)] *paragraphs (1), (2), and (3)(B)* of this subsection, amend or revoke a performance standard.

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PREMARKET APPROVAL

General Requirement

Sec. 515. (a) * * *

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(3)(A) The Secretary may by order suspend the approval of an application approved under this section if the Secretary determines that there is a reasonable probability that the continued distribution of a device under the application would cause serious, adverse health consequences or death.

(B) Not less than 10 days prior to the issuance of a suspension order under subparagraph (A), the Secretary shall issue a notice that the Secretary shall provide the holder of the application for the device with an opportunity for an informal hearing to determine whether to issue the order.

(C) Not more than 10 days after the hearing described in subparagraph (B), the Secretary shall issue a suspension order or determine that the order should not be issued.

(D) Not more than 20 days after the issuance of the suspension order, the Secretary shall issue a notice initiating the process of withdrawal of approval of the application, as described in paragraphs (1) and (2). If the Secretary does not issue the

notice within the specified time frame, the suspension order shall be deemed to be vacated.

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JUDICIAL REVIEW

Application of Section

SEC. 517. (a) * * *

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(3) the issuance of an order under section [514(b)(2) or] 515(b)(2)(B) denying a request for reclassification of a device,

* * * * * * *

(6) the issuance of an order under section 520(f)(2), [or]

* * * * * * *

(8) the issuance of a regulation under section 513(h), or

(9) the issuance of an order under section 513(f)(1) or an order effectuating the classification required under 520(l)(1)(D).

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NOTIFICATION AND OTHER REMEDIES

Notification

SEC. 518. (a) * * *

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Emergency Recall Authority

(e)(1) If the Secretary finds that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death, the Secretary shall issue a recall order. The order shall require the appropriate party or parties (including the manufacturers, importers, distributors, or retailers of the device) to immediately cease any distribution of the device and, thereafter, recall the device from commercial distribution.

(2)(A) The order issued under paragraph (1) shall include recall of devices from hospitals and other health care institutions, unless the Secretary determines that the risk of recalling the device from the facilities presents a greater health risk than not recalling the device from use.

(B) For devices subject to an order issued under paragraph (1), and in lieu of including individuals within the recall order, the Secretary shall order a notification under subsection (a) regarding the risks associated with the continued use of the device to individuals or, when appropriate, the health professionals who prescribed the device for the use of the individuals.

(3) Not later than 10 days after the issuance of a recall order, the Secretary shall provide the party or parties to whom the order is directed with the opportunity for an informal hearing to determine whether the order shall be affirmed or vacated.

(4) If, after providing an opportunity for an informal hearing, the Secretary determines that the recall order was properly issued, the

order shall remain in effect. The order shall specify a timetable in which the device recall will occur, and shall require periodic reports to the Secretary describing the progress of the recall effort.

(5) If, after providing an opportunity for an informal hearing, the Secretary determines that inadequate grounds exist to support the order issued under paragraph (1), the Secretary shall vacate the order.

(6) A party to whom the recall order is issued shall—

(i) remedy the causes that resulted in the issuance of the order;

(ii) complete the recall in accordance with the order; and

(iii) submit a report to the Secretary demonstrating compliance with the order.

(7) After fulfilling the requirements of paragraph (6), a party to whom the recall order is issued may petition the Secretary to vacate the order. The petition shall state the basis for vacating the order.

(8) The Secretary shall respond to the petition described in paragraph (7) not later than 30 days after the receipt of the petition. If the Secretary finds that the party to whom the recall order was issued has fulfilled the requirements of paragraph (6) and that the device may be distributed in interstate commerce, the Secretary shall vacate the order.

(9) The remedy provided by this subsection shall be in addition to those provided by subsections (a), (b), and (c).

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RECORDS AND REPORTS ON DEVICES

General Rule

SEC. 519. (a) * * *

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(3) which require submission of a report or information to the Secretary shall state the reason or purpose for the submission of such report or information and identify to the fullest extent practicable such report or information *and shall require distributors who submit the reports to submit copies of the reports to the manufacturer of the device for which the report was made;*

* * * * * * *

Inclusion of Distributors

(c) Not later than 1 year after the date of the enactment of this subsection, the Secretary shall amend the regulations promulgated under this section to require distributors of medical devices to establish and maintain records and make reports under this section. In amending the regulations, the Secretary may exempt classes of distributors from whom reports are not necessary for the protection of public health.

Certification

(d) Each manufacturer, importer, and distributor required to make reports under subsection (a) shall submit to the Secretary annually a statement certifying that the manufacturer, importer, or distributor—

(1) did not file any report; or

(2) did file a certain number of the reports.

User Reports

(e)(1) As used in this subsection:

(A) The terms "facility" and "medical device user facility" mean a hospital, nursing home, or ambulatory surgical facility.

(B) The terms "serious illness" and "serious injury" mean illness or injury, respectively, that is unanticipated and—

(i) is life threatening;

(ii) results in permanent impairment of a body function or permanent damage to a body structure; or

(iii) necessitates immediate medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

(2) If a medical device user facility becomes aware of information that reasonably suggests that a medical device has caused or contributed to the death of a patient of the facility, the facility shall, as soon as practicable but not later than 15 working days after becoming aware of the information, report the information to the Secretary and, if the identity of the manufacturer is known, to the manufacturer of the device.

(3) If a medical device user facility becomes aware of information that reasonably suggests that a medical device has caused or contributed to a serious illness or serious injury to a patient of the facility, the facility shall, as soon as practicable, but not later than 15 working days after becoming aware of the information, report the information to the manufacturer of the device. If the facility is unable to determine the identity of the manufacturer of the device, the facility shall send a report of the information to the Secretary.

(4) For purposes of paragraphs (2) and (3), a medical device user facility shall be treated as having received or otherwise become aware of information with respect to a medical device of the facility when appropriate medical personnel employed by or otherwise affiliated with the facility receive or otherwise become aware of information with respect to the device in the course of the duties of the individual.

(5)(A) Except as provided in subparagraph (B), the Secretary may not disclose the identity of a facility that makes a report in accordance with paragraph (2) or (3)—

(i) except in connection with an action brought to enforce section 301(q);

(ii) except in connection with a communication to a manufacturer of a device that is the subject of a report in accordance with paragraph (2) or (3); or

(iii) unless required to be disclosed in accordance with subsection (a).

(B) This paragraph shall not authorize the Secretary to withhold the identity of a facility making a report in accordance with paragraph (2), or any information in the report, from duly authorized committees and subcommittees of Congress.

(6)(A) No report made in accordance with paragraph (2) or (3) by a person described in subparagraph (B) shall be admitted into evidence in any civil action involving private parties unless the person had knowledge of the falsity of the information contained in the report.

(B) As used in subparagraph (A), the term "person" means—

(i) a medical device user facility;

(ii) one of the appropriate medical personnel employed by or otherwise affiliated with the facility; or

(iii) a physician who is not required to make a report in accordance with paragraph (2) or (3).

(7) The obligation of a medical device user facility to make a report in accordance with paragraph (2) or (3) shall not affect the obligation of the manufacturer of the device who receives the information to file a report concerning the device as required under subsection (a).

User Education

(f)(1) During the 1-year period beginning on the date of enactment of this subsection, the Secretary may award grants to eligible entities to establish public education programs for hospitals, ambulatory surgical facilities, and nursing homes concerning the user reporting requirements set forth in subsection (e).

(2) In awarding grants in accordance with paragraph (1), the Secretary shall give priority to entities to submit proposals that demonstrate—

(A) a need for user education among hospitals, ambulatory surgical facilities, and nursing homes regarding a generic category of medical device; and

(B) the ability to adequately perform the proposed educational program.

(3) In order to receive a grant in accordance with paragraph (1), an entity shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may by regulation require. At a minimum, the application shall contain—

(A) a description of the proposed public education program;

(B) the qualifications and experience of the entity to carry out the program; and

(C) the need for user education among persons to be served by the entity regarding a generic category of medical device.

(4) The Secretary shall by regulation specify the qualifications for an entity to receive a grant in accordance with paragraph (1).

(5) There are authorized to be appropriated to carry out this subsection such sums as may be necessary for each of fiscal years 1991 through 1993.

Reports of Removals and Corrective Actions

(g)(1)(A) Except as provided in paragraph (2), the Secretary shall by regulation require a manufacturer, importer, or distributor of a device to report promptly to the Secretary any removal or corrective action of a device undertaken by the manufacturer, importer, or distributor of a device if the removal or corrective action was undertaken to—

(i) eliminate a significant risk to health caused by the device; or

(ii) remedy a violation of this Act caused by the device which may present a risk to health.

(B) A manufacturer, importer, or distributor of a device who undertakes a corrective action or removal of a device that is not required to be reported under subparagraph (A) shall keep a record of the corrective action or removal.

(2) No report of the corrective action or removal of a device may be required under paragaraph (1) if a report of the corrective action or removal is otherwise required under this Act, or the corrective action or removal was initiated at the request of the Secretary, and a report has been submitted to the agency.

(3) For purposes of paragraphs (1) and (2), the terms "corrective action" and "removal" do not include routine servicing.

GENERAL PROVISIONS RESPECTING CONTROL OF DEVICES INTENDED FOR HUMAN USE

General Rule

SEC. 520. [360j] (a) * * *

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Trade Secrets

(c) Any information reported to or otherwise obtained by the Secretary or his representative under section 513, 514, 515, 516, 518, 519, or 704 or under subsection (f) or (g) of this section which is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of such section shall be considered confidential and shall not be disclosed and may not be used by the Secretary as the basis for the reclassification of a device [under section 513 from class III to class II] *from class III to class II or class I* or as the basis for the establishment or amendment of a performance standard under section 514 for a device reclassified from class III to class II, except *in accordance with subsection (h) and* that such information may be disclosed to other officers or employees concerned with carrying out this Act or when relevant in any proceeding under this Act (other than section 513 or 514 thereof).

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Release of Safety and Effectiveness Information

(h)(1) * * *

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(3) [Any] *Except as provided in paragraph (4), any* information respecting a device which is made available pursuant to paragraph (1) or (2) of this subsection (A) may not be used to establish the safety or effectiveness of another device for purposes of this Act by any person other than the person who submitted the information so made available, and (B) shall be made available subject to subsection (c) of this section.

(4)(A) Any information contained in an application for premarket approval filed with the Secretary pursuant to section 515(c), including clinical and preclinical tests or studies, but excluding descriptions of methods of manufacture and product composition, that demonstrates the safety and effectiveness of a device shall be available 1 year after the original application for the fourth device of a kind has been approved by the Secretary, for use by the Secretary in approving devices, or determining whether a product development protocol has been completed, under section 515, establishing a performance standard under section 514, and reclassifying devices under subsections (e) and (f) of section 513, and subsection (l)(2). The Secretary shall deem devices that incorporate the same technologies, have the same principles of operation, and are intended for the same use or uses to be within a kind of device.

(B) The Secretary, contemporaneously with the approval of the fourth device of a kind, shall publish a notice in the Federal Register identifying the four devices of a kind that have been approved under section 515 and the date on which the data contained in premarket approval applications for the devices will be available to the Secretary for use, as described in subparagraph (A). For each device described in subparagraph (D)(i)(I), the Secretary shall publish a notice in the Federal Register setting forth the date, which shall be not earlier than 1 year after the date of notice, that data indentified in subparagraph (A) shall be available for the use of the Secretary.

(C) The publicly available detailed summaries of information respecting the safety and effectiveness of devices required by paragraph (1)(A) shall be available for use by the Secretary as the evidentiary basis for—

(i) approving devices, or determining whether a product development protocol has been completed, under section 515;

(ii) establishing a performance standard under section 514; and

(iii) reclassifying devices under subsections (e) and (f) of section 513, and subsection (l)(2).

(D)(i) This paragraph shall become effective—

(I) upon the date of the enactment of the paragraph, for devices approved under section 515, where four devices of a kind were approved on or before December 31, 1987; and

(II) 24 months after the date of the enactment of the paragraph, for devices not included within the scope of subclause (I) that are subject to a premarket approval requirement under section 515.

(ii) For each device described in subparagraph (D)(i)(II) for which the original application for a fourth device of a kind is approved by the Secretary before the 24-month delayed effective date described in subparagraph (D)(i)(II), the 24-month delayed effective date shall be deemed to be the approval date for the fourth device of a kind.

(E) The approval date of a device, for purposes of this paragraph, shall be the date of the letter of the Secretary to the applicant approving a device under section 515, and permitting the applicant to commercially distribute the device.

Proceedings of Advisory Panels and Committees

(i) Each panel under section 513 and each advisory committee established under section [514(g)(5)(B)] *514(b)(5)(B)* or 515(g) or under subsection (f) of this section shall make and maintain a transcript of any proceeding of the panel or committee. Each such panel and committee shall delete from any transcript made pursuant to this subsection information which under subsection (c) of this section is to be considered confidential.

[Traceability Requirements

[(j) No regulation under this Act may impose on a type or class of device requirements for the traceability of such type or class of device unless such requirements are necessary to assure the protection of the public health.]

Traceability Requirements

(j)(1) The Secretary shall, not later than 1 year after the date of enactment of this subsection, determine which devices should be subject to a requirement of labeling, or coding, or identification by any other means, that is necessary to ensure that the device may be traced from the place of manufacture of the device or initial distribution to the ultimate user of the device, from among devices that—

(A) are permanent implants;

(B) are purported or represented to be for use in supporting or sustaining human life; or

(C) present a potential unreasonable risk of illness or injury.

(2) Not later than 2 years after the date of enactment of this subsection, the Secretary shall by regulation require the manufacturers, importers, and distributors of the devices that are described in paragraph (1) to establish the means by which the devices will be traced to the ultimate user.

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Transitional Provisions for Devices Considered as New Drugs or Antibiotic Drugs

(l)(1) * * *

* * * * * * *

is classified in class III unless the Secretary *on the initiative of the Secretary or* in response to a petition submitted under [paragraph (2)] *paragraph (2)(A)* has classified such device in class I or II.

(2)*(A)* [The] *The Secretary may initiate the reclassification of a device classified in class III under paragraph (1), or a* manufacturer or importer of a device classified under paragraph (1) may petition the Secretary (in such form and manner as he shall prescribe) for the issuance of an order classifying the device in class I or class II. Within thirty days of the filing of such a petition, the Secretary shall notify the petitioner of any deficiencies in the petition which prevent the Secretary from making a decision on the petition. Except as provided in paragraph (3)(D)(ii), within one hundred and eighty days after the filing of a petition under this paragraph and after affording the petitioner an opportunity for an informal hearing, the Secretary shall, after consultation with the appropriate panel under section 513, by order either deny the petition or order the classification, in accordance with the criteria prescribed by section 513(a)(1)(A) or 513(a)(1)(B), of the device in class I or class II.

(B)(i) Not later than 90 days after the date of enactment of this subparagraph, the Secretary shall publish a notice in the Federal Register with respect to devices that are subject to regulation pursuant to this subsection. The notice shall state whether each device shall remain in class III or be reviewed for classification into class I or II. The notice shall also require the manufacturer of a device that the Secretary intends to classify into class I or II to submit to the Secretary a description of and citation to any adverse safety and effectiveness information not submitted under section 519(a) of this Act and section 803 of title 21, Code of Federal Regulations. The Secretary may require a manufacturer to submit the adverse safety and effectiveness information for which a description and citation were submitted to the Secretary.

(ii) After the issuance of the notice under clause (i), and following consultation with appropriate advisory panels in accordance with subsections (b) through (d) of section 513, but before the expiration of the 1-year period beginning on the date of enactment of this subparagraph, the Secretary shall publish a proposed regulation in the Federal Register classifying each device into class I or II, or providing that each device shall remain in class III. The data furnished by manufacturers in accordance with clause (i), in combination with the advice and recommendation of appropriate advisory panels shall, for purposes of this Act, serve as a basis for satisfying the criteria set forth in subclause (I) or (II) of section 513(a)(C)(ii), and shall serve as a basis for the proposed regulation required under this subparagraph.

(iii) Following a review of comments received on the proposed regulation issued in accordance with clause (ii), and before the expiration of the 1-year period referred to in clause (ii), the Secretary shall promulgate a final regulation prescribing the classification of all devices regulated under this subsection on the date of enactment of this subparagraph. No regulation issued under this subparagraph requiring a device to remain in class III or classifying the device as class I or II may take effect before the expiration of 90 days from the date of the publication of the regulation in the Federal Register.

(iv) The Secretary may by notice in the Federal Register extend the 1-year period prescribed by clauses (ii) and (iii) for a device for an additional period not to exceed 1 year.

(v) Notwithstanding any other provision of this subsection, the Secretary shall not retain any daily wear nonhydrophilic plastic contact lens in class III unless the Secretary finds that it meets the criteria set forth in subclause (I) or (II) of section 513(a)(1)(C)(ii). The finding, and the grounds for the finding, shall be published in the Federal Register. If during the 1-year period beginning on the date of enactment of this subparagraph, the Secretary has not made the finding and issued the notice required by this clause, the Secretary shall issue an order placing the lens in class II.

(vi) Actions taken under this paragraph shall interfere with any pending reclassification action. Any device for which a reclassification petition was pending on January 1, 1989, shall not be included in the list published under clause (i).

* * * * * * *

Substantial Equivalence

(m)(1) For purposes of determinations of substantial equivalence under this subchapter—

(A) The term "different technological characteristics" means, with respect to a device being compared to a predicate device, that there is a significant change in the materials, design, energy source, or other features of the device from those of the predicate device.

(B) The term "substantially equivalent" or "substantial equivalence" means, with respect to a device being compared to a predicate device, that the device has the same intended use as the predicate device and—

(i) has the same technological features as the predicate device; or

(ii) has different technological features and the evidence submitted that the device is substantially equivalent to the predicate device contains information, including clinical data, if required, that demonstrates that the device is as safe and effective as a marketed device.

(2) A device may not be found to be substantially equivalent to a predicate device that has been removed from the market at the initiative of the Secretary or that has been determined to be misbranded or adulterated by a judicial order.

(3) The Secretary shall promulgate regulations under which a manufacturer seeking a determination of substantial equivalence may be required to prepare a summary of any clinical data required (including information respecting any adverse effects of the device on health) if the Secretary determines that clinical data must be submitted in accordance with paragraph (1)(B)(ii), and establishing a standard format for the summary. The Secretary shall make the summary available to the public within 30 days of the issuance of a determination of substantial equivalence.

Humanitarian Devices

(n)(1) It is the purpose of this subsection to encourage the discovery of devices intended to benefit patients in the treatment or diagnosis of rare diseases or conditions, to the extent consistent with the

protection of the public health and safety and with ethical standards.

(2) As used in this subsection, the term "rare disease or condition" means any disease or condition that affects fewer than 8,000 persons in the United States. Determinations under the previous sentence with respect to any device shall be made on the basis of the facts and circumstances as of the date of submission of an application under paragraph (3).

(3) Not later than 8 months after the date of enactment of this subsection, the Secretary shall promulgate regulations prescribing procedures and conditions under which persons may on application be granted an exemption for devices from the effectiveness requirements of section 502, 514, 515, 516, 519, or 706, or subsection (e) or (f) of this section, to permit the use of the devices by physicians in the treatment of patients afflicted by a rare disease or condition.

(4) In promulgating regulations under paragraph (3), the Secretary may prescribe procedures and conditions under which an exemption may be granted for a device if—

(A) the device is likely to provide a significant benefit to a patient in the treatment or diagnosis of a disease or condition, or a significant benefit to the patient in quality of life;

(B) the device is used—

(i) in the treatment or diagnosis of a rare disease or condition and cannot reasonably by expected to be available absent the exemption; or

(ii) the patient population affected by the disease or condition is not sufficient to conduct clinical trials of the effectiveness of the device; and

(C) the Secretary determines that the probable benefit to health from the use of the device outweighs the risk of injury or illness from the use and the probable risks and benefits of currently available devices or alternative forms of treatment.

(5) Devices granted an exemption under this subsection shall only be used—

(A) in facilities that have established, in accordance with regulations of the Secretary, a local institutional review committee to supervise clinical testing of devices in the facilities; and

(B) if, prior to the use of a device, an institutional review committee approves the use in the treatment or diagnosis of a specific rare disease or condition.

STATE AND LOCAL REQUIREMENTS RESPECTING DEVICES

General Rule

SEC. 521. (a) * * *

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SEC. 522. POSTMARKET SURVEILLANCE.

(a) IN GENERAL.—

(1) REQUIRED SURVEILLANCE.—The Secretary shall require a manufacturer to conduct postmarket surveillance for any device that—

(A) is a permanent implant the failure of which may cause serious, adverse health consequences or death;

(B) is intended for a use in supporting or sustaining human life; or

(C) presents potential for serious risk to human health.

(2) DISCRETIONARY SURVEILLANCE.—The Secretary may require a manufacturer to conduct postmarket surveillance for a device if the Secretary determines that postmarket surveillance of the device is necessary to protect the public health or to evaluate the safety or effectiveness of the device.

(b) REGULATIONS.—The Secretary shall issue regulations implementing the requirements of this section not later than 1 year after the date of enactment of this section.

(c) SURVEILLANCE PERIOD.—The Secretary may determine the period of surveillance required in order to complete the collection of useful data or other information necessary to protect the public health or to evaluate the safety or effectiveness of the device. In no event may a surveillance period be imposed in accordance with this section without a termination date.

(d) CONTRACTS.—

(1) IN GENERAL.—The manufacturer of a device for which postmarket surveillance is required in accordance with subsection (a) shall contract with a qualified academic medical center, or a representative number of qualified academic medical centers in representative locations, to provide for any monitoring of clinical experience that may be required in accordance with this section.

(2) LACK OF QUALIFIED ACADEMIC MEDICAL CENTER.—If no academic medical center has the qualifications and experience to conduct adequate monitoring of clinical experience in accordance with this section, a manufacturer shall contract with a qualified medical center or with a representative number of qualified medical centers in representative locations to provide the monitoring.

(3) NUMBER AND IDENTITY.—The manufacturer shall determine, and obtain the approval of the Secretary regarding, the number and identity of the center or centers that will perform surveillance in accordance with this section and the manner of surveillance.

(e) APPLICATION.—This section shall apply only to devices that are first distributed in interstate commerce after the date of enactment of this section.

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TITLE 21, UNITED STATES CODE

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FOOD AND DRUGS

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Subchapter VIII—Imports and Exports

§ 381. Imports and exports

(a) Imports; list of registered foreign establishments; samples from unregistered foreign establishments; examination and refusal of admission.

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(f)(1) The Secretary may enter into agreements with foreign governments, which agreements specify that devices of either country that are manufactured in accordance with rules and regulations for device manufacture under this Act are suitable for commercial distribution.

(2) In entering into the agreements described in paragraph (1), the Secretary shall encourage the mutual recognition of—

(A) good manufacturing practice regulations promulgated under section 520(f)(1)(A); and

(B) other rules, regulations, and testing protocols as the Secretary determines to be appropriate.

(3) The Secretary shall establish an Office of International Relations that shall plan and initiate programs for the recognition of devices in accordance with paragraph (1).

(4) The Secretary may issue regulations to carry out this subsection.

(5) Not later than 2 years after the date of enactment of this subsection, the Secretary shall prepare and sumbit to the appropriate committees of Congress a report on the activities of the Office of International Relations.

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TITLE 35, UNITED STATES CODE

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PATENTS

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§ 156. Extension of patent term

(a) * * *

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(2) the term of the patent has never been extended, *except as otherwise provided in subsection (i)*;

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The product referred to in paragraphs (4) and (5), *and in subsection (i)* is hereinafter in this section referred to as the "approved product".

* * * * * * *

(i)(1) Notwithstanding the provisions of subsection (a)(2), if a claim or claims of any patent on an invention that was conceived or reduced to practice substantially in the performance of work at a nonprofit organization cover more than one product, or a method of

using or manufacturing more than one product, that is subject to a regulatory review period before the commercial marketing or use of the product, the claim or claims may be separately extended as to each of the products in accordance with this section.

(2) In no event may any extensions granted under this subsection extend the term of a patent claim in respect of a product other than a product for which extension is sought.

(3) As used in this subsection, the term "nonprofit organization" has the meaning given the term in section 201(i).

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